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JUEVES, 23 OCTUBRE 2025

Hepatocellular Carcinoma and Liver Transplantation from Milan criteria to personalized indications



UNIVERSITÀ
DEGLI STUDI
DI MILANO

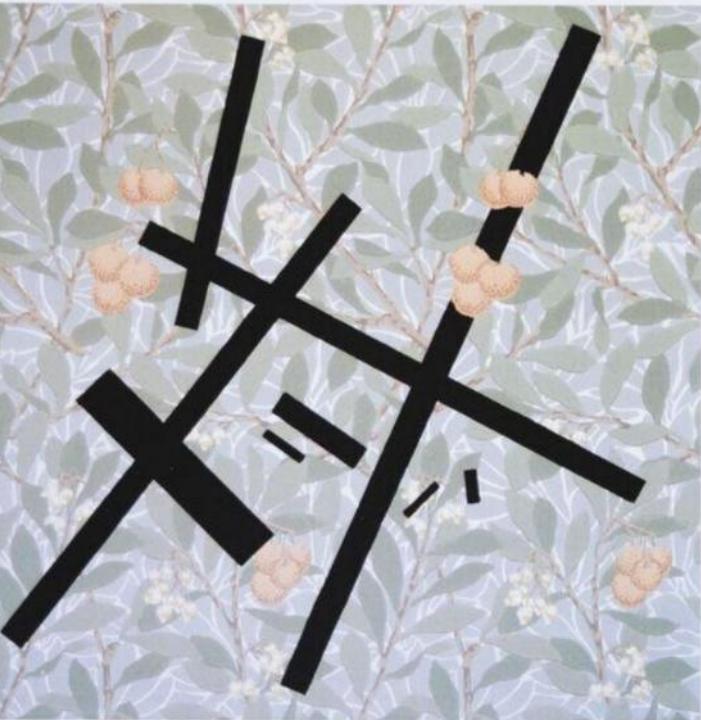
Vincenzo Mazzaferro MD PhD
University of Milan
Istituto Nazionale dei Tumori Milan, Italy



**FONDAZIONE IRCCS
ISTITUTO NAZIONALE
DEI TUMORI**

(I have no conflict of interest in the contest of the subject of this presentation)

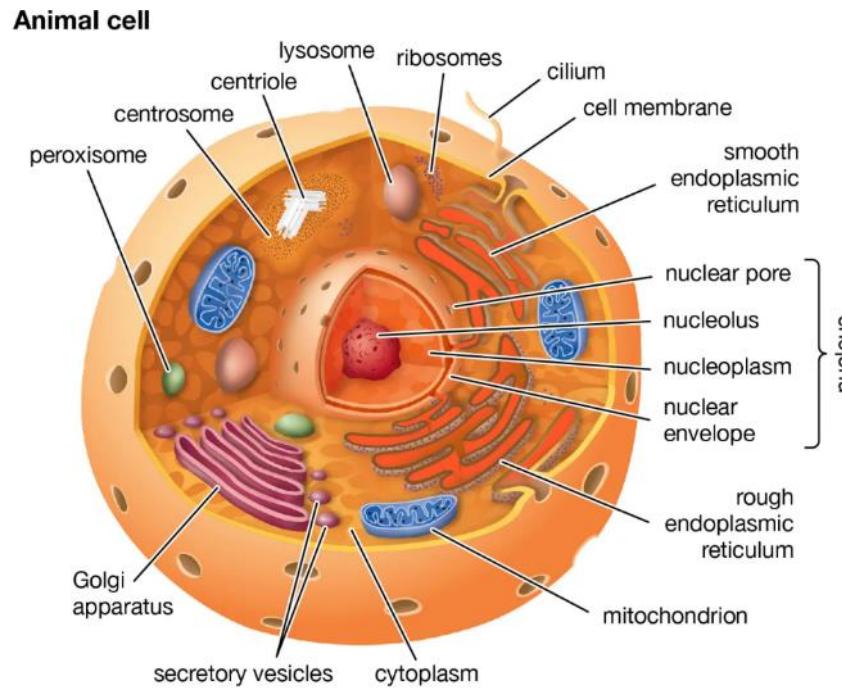
limits, barriers and borders



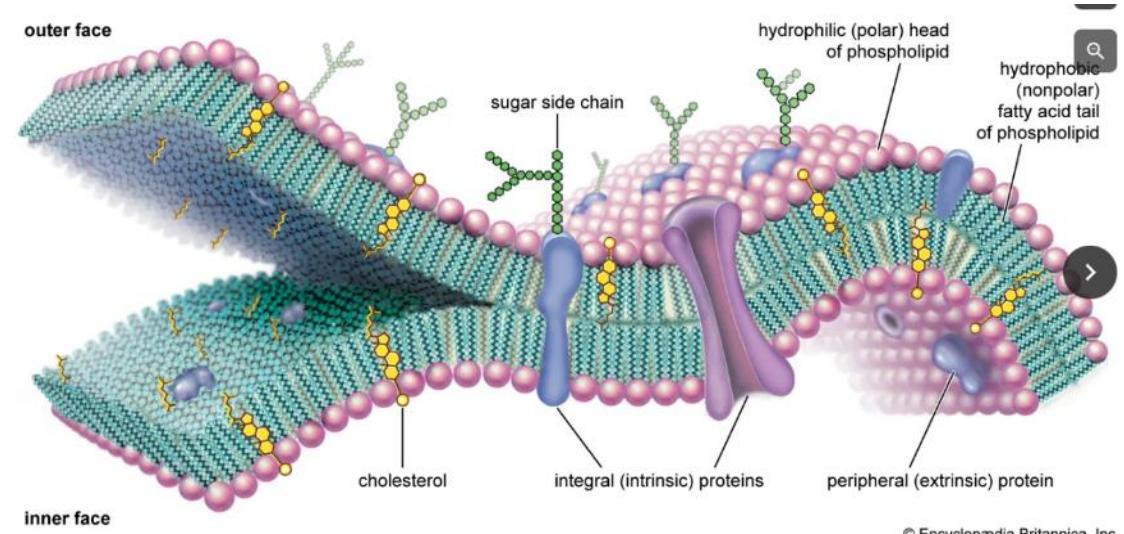
historical materialism
www.historicalmaterialism.org
2016 annual conference



Complex living systems are thought to exist at the “edge of chaos” separating the ordered dynamics of robust function from the disordered dynamics of rapid environmental adaptation.



Boundaries are an essential part of life since life only exists on the edge of chaos



Bringing order and organization to the chaos depends on membrane-bound compartments

The new era of Liver Transplantation for hepatic malignancies



Latest Europe World EU Policy Business Travel Next Culture Green Health



SC

Article

Gene-modified pig-to-human liver xenotransplantation

<https://doi.org/10.1038/s41586-025-08799-1>

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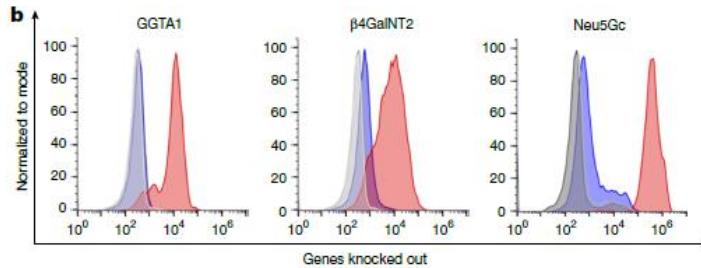
Open access

Check for updates

Kai-Shan Tao^{1,6}, Zhao-Xu Yang^{1,16}, Xuan Zhang^{1,16}, Hong-Tao Zhang^{1,16}, Shu-Qiang Yue¹, Yan-Ling Yang¹, Wen-Jie Song¹, De-Sheng Wang¹, Zheng-Cai Liu¹, Hai-Min Li¹, Yong Chen¹, Rui Ding¹, Shi-Ren Sun², Ming Yu³, Ji-Peng Li⁴, Wei-Xun Duan⁵, Zhe Wang⁶, Jing-Wen Wang⁷, Jia-Yun Liu⁸, Min-Wen Zheng⁹, Xi-Jing Zhang^{10,11}, Wen Yin¹², Wei-Jun Qin¹³, Dong-Mei Bian¹⁴, Lin Li¹, Min Li¹, Zhi-Bin Lin¹, Hao Xu¹, Dan Wei¹, Hong Zhang¹, Juan-Li Duan¹, Deng-Ke Pan¹⁵, Hai-Long Dong^{11,16}, Lin Wang^{1,16} & Ke-Feng Dou^{1,16}

The shortage of donors is a major challenge for transplantation; however, organs from genetically modified pigs can serve as ideal supplements^{1,2}. Until now, porcine hearts and kidneys have been successively transplanted into humans^{3–7}. In this study, heterotopic auxiliary transplantation was used to donate a six-gene-edited pig liver to a brain-dead recipient. The graft function, haemodynamics, and immune and

a



Home > Health > Health news

World's first pig-to-human liver transplant keeps patient alive for 171 days



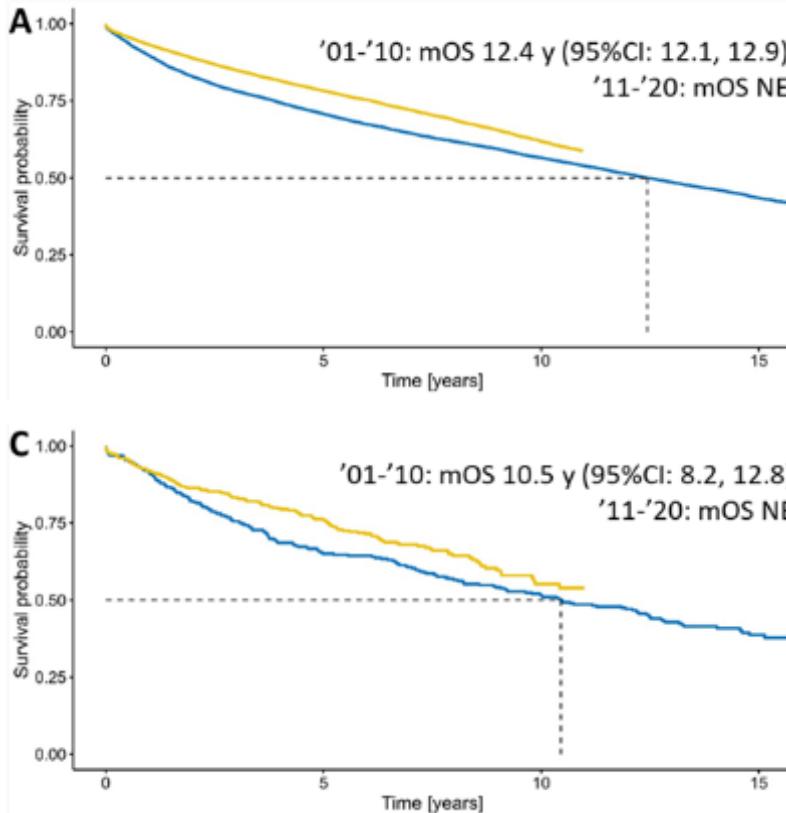
Copyright Shelby Lum/AP Photo

By [Theo Farrant](#)

Published on 09/10/2025 - 6:02 GMT+2 • Updated 9:34

Despite strong learning attitude and open disposition to science liver transplantation for cancer remains a procedure at high cost, **limited in competitiveness by the distance between incidence of liver cancers and availability of donated organs**

The new era of Liver Transplantation for hepatic malignancies



deceased donor
within Milan criteria

deceased donor
beyond Milan criteria

Pre-transplant therapies in this cohort include ablation (42%), TACE (30%), TARE (3%), resection (0.7%) and SBRT (0.6%)

Magyar CTJ et al. J Clin Oncol 2025



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Home > Health > Health news

World's first pig-to-human liver transplant keeps patient alive for 171 days



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By [Theo Farrant](#)

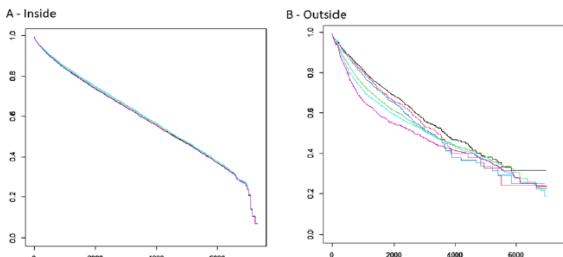
Published on 09/10/2025 - 6:02 GMT+2 • Updated 9:34

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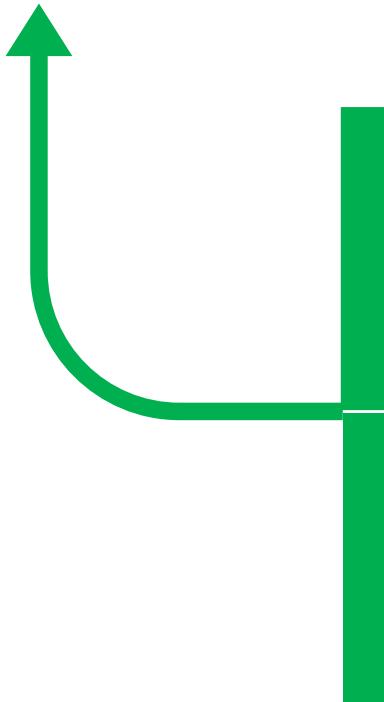
Time to Expand Selection Criteria for MELD Exception Points in Liver Transplantation for Hepatocellular Carcinoma

Chase J. Wehrle, MD,¹ Jiro Kusakabe, MD, PhD, MPH,² Toshihiro Nakayama, MD,³ Charles Miller, MD,¹ Koji Hashimoto, MD, PhD,¹ Timothy M. Pawlik, MD, PhD, MPH,⁴ Kazunari Sasaki, MD, PhD,³ Vincenzo Mazzafferro, MD, PhD,⁵ Andrea Schlegel, MD, MPH,¹ and Federico Aucejo, MD,¹

National Cohort, Overall Survival



Wehrle CJ et al. Transplantation 2025



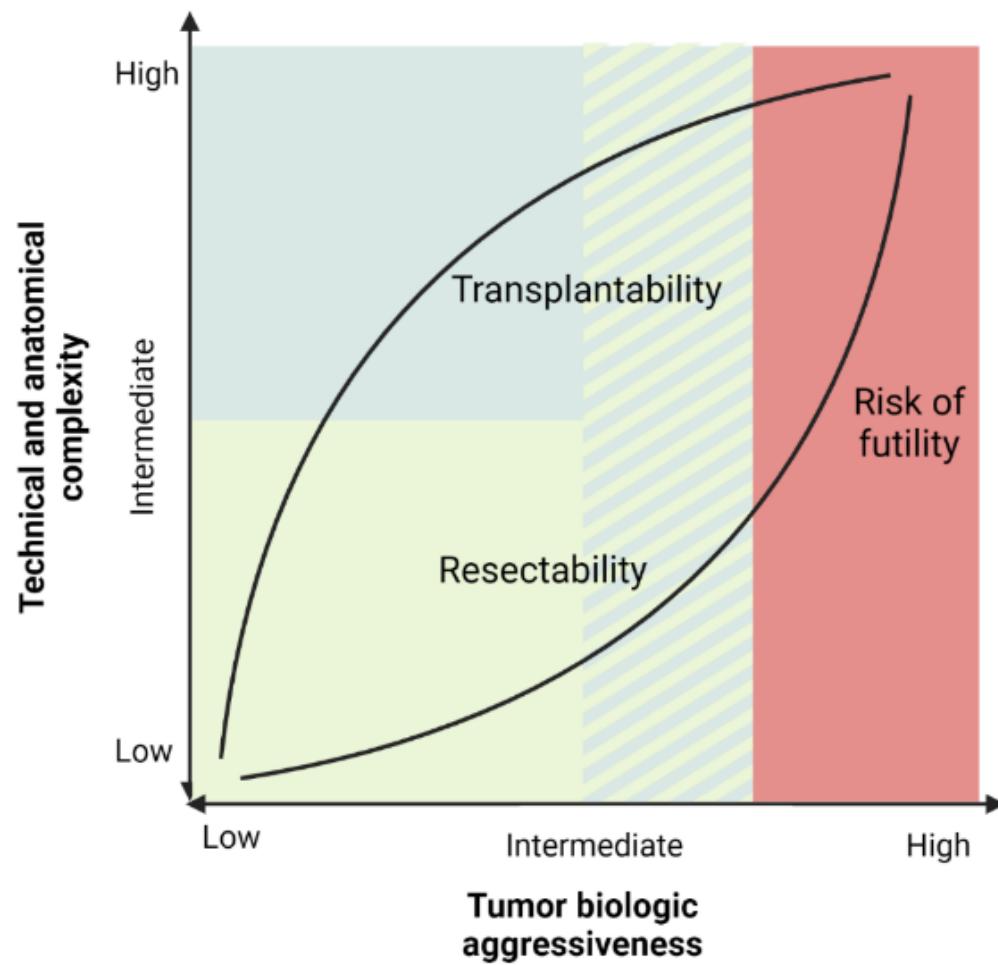
Transplantation ■ March 2021 ■ Volume 105 ■ Number 3

www.transplantjournal.com

TABLE 1.

Consensus recommendations for the expansion of liver transplant indications in Spain

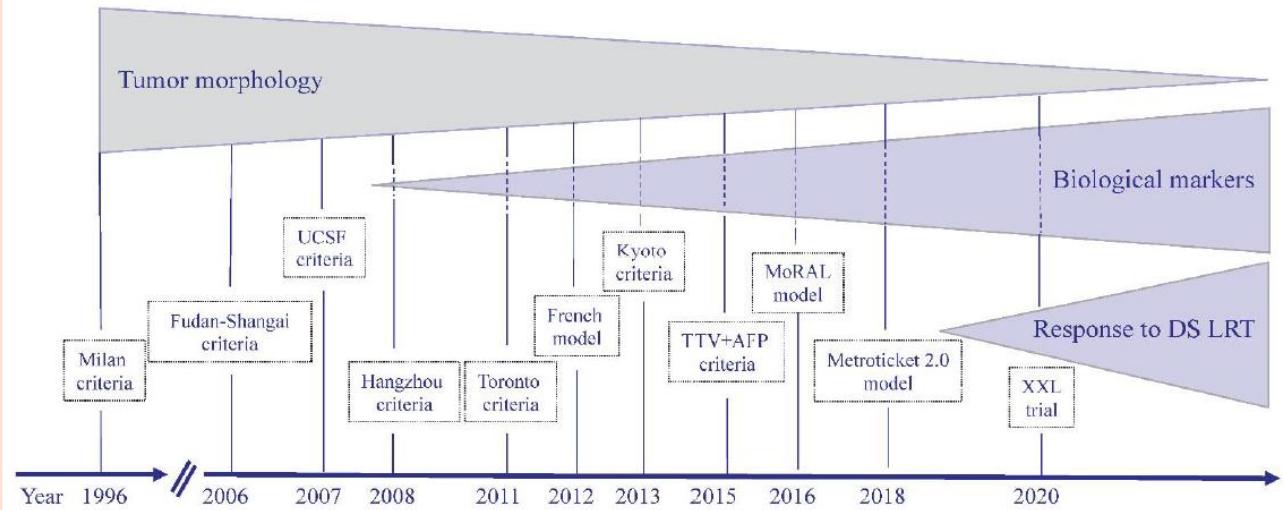
Recommendations	GRADE	Ref.
2. Hepatocellular carcinoma		
2.1 The presence of extrahepatic metastases or macrovascular invasion should preclude LT in patients with cirrhosis and hepatocellular carcinoma.	1A	18-22
2.2 Milan criteria are considered the standard of care to select candidates with hepatocellular carcinoma for LT.	1A	7,23
2.3 Patients within Milan criteria showing AFP >1000 ng/mL should undergo locoregional therapy to ensure a decline of AFP below 500 ng/mL to be included in the waiting list. If AFP remains >500 ng/mL, LT should be discouraged.	2C	24
2.4 A moderate expansion of Milan criteria is advised as long as the balance with other indications of LT is preserved.	1B	25,26
2.5 Among the expanded criteria for LT, the "Up-to-7" criteria are those with the strongest scientific background and may be preferred over other systems.	2B	27,28
2.6a Patients beyond Milan but within "Up-to-7" criteria with serum AFP >400 ng/mL should undergo <u>locoregional therapy</u> with complete restaging 1 mo later, before being included in the waiting list (see recommendation 2.6b).	2B	29,30
2.6b In patients beyond Milan but within "Up-to-7" without radiological response after <u>locoregional therapy</u> (partial or complete as defined by RECIST 1.1 criteria) and progressive increase of serum AFP despite locoregional therapy, LT should be contraindicated.	2C	31-33
2.7 The above-referred recommendations do not apply to downstaging strategies. Given the <u>heterogeneity and complexity</u> of the scientific evidence around this practice, a dedicated consensus document is warranted.	2C	N/A



... at similar (active) tumor burden

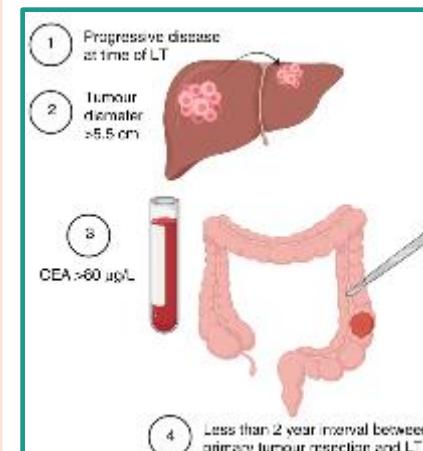
Mazzaferro V et al. Transplant Oncology (Ed M Abdelrahim) 2024; Adam R et al. Lancet 2024; Dueland S et al. JAMA Surg. 2023; Bonney GK et al. Lancet Gastro Hep 2021;

Primary liver cancer (HCC)

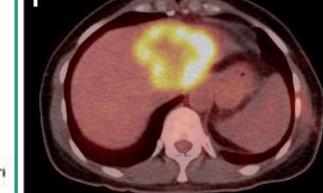


Liver mets (CRLM)

Oslo Score



c PET MTV



TransMet criteria

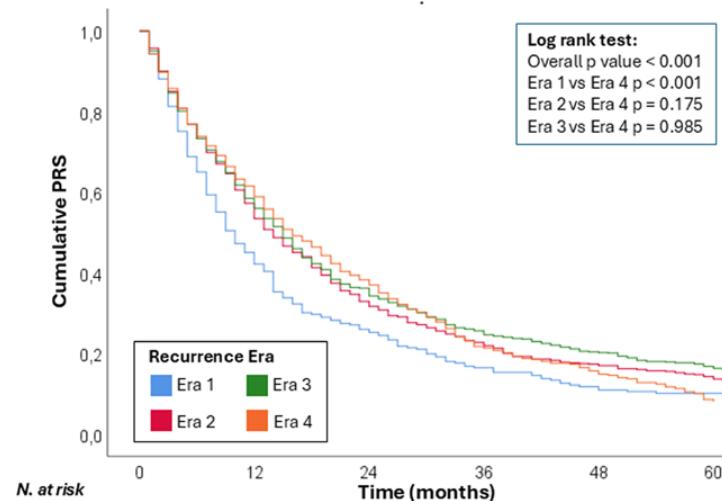
Supplementary Table S2 (online only): Eligibility criteria	
Eligibility	Details
Inclusion criteria	<ul style="list-style-type: none"> - ≥ 18 and ≤ 65 years - Good performance status: ECOG 0 or 1 (39) - Histologically proved adenocarcinoma in colon or rectum - BRAF wild-type CRC on primary tumor or hepatic metastases - High standard oncological surgical resection of the primary defined by: <ul style="list-style-type: none"> o Safe margin of resection o Removal of primary tumor according to oncological principles - Absence of local recurrence on colonoscopy performed in the 12 months prior to inclusion (except in case of primary resection < 12 months) - Confirmed resectable liver metastases of colorectal cancer by the validation committee - ≥ 3 months of overall control during the last chemotherapy line: Stable or Partial Response on RECIST criteria (40) - ≥ 3 lines of chemotherapy for metastatic disease - CEA < 80 ng/mL or a decrease ≥ 50% of the highest serum CEA levels observed during the disease - Absence of metastatic cancer localization according to CT scan and PET-CT - Renal function should be within the normal limits - No need for extra-renal purification procedure, hemodialysis or kidney transplantation associated (nephrologist evaluation) - A platelet count: 80,000/mm³ - White blood cell count: 2500/mm³ - Eligible for both treatment groups - Signed informed consent and expected cooperation of the patient for the treatment and follow up
Non-inclusion criteria	<ul style="list-style-type: none"> - Participation refusal - No health insurance facilities - General contraindication to LT (Severe cardiopulmonary disease or other life-limiting active infections or uncontrolled sepsis, lack of psychosocial support or inability to comply with medical treatment) - Other malignancies either concomitant or within 5 years before liver transplantation - Patients not having received high standard oncological surgery of the primary CRC according to recommended guidelines* - Prior extra hepatic metastatic disease or local relapse - Pregnancy at the time of inclusion

Post-recurrence Survival after Liver Transplantation for Hepatocellular Carcinoma

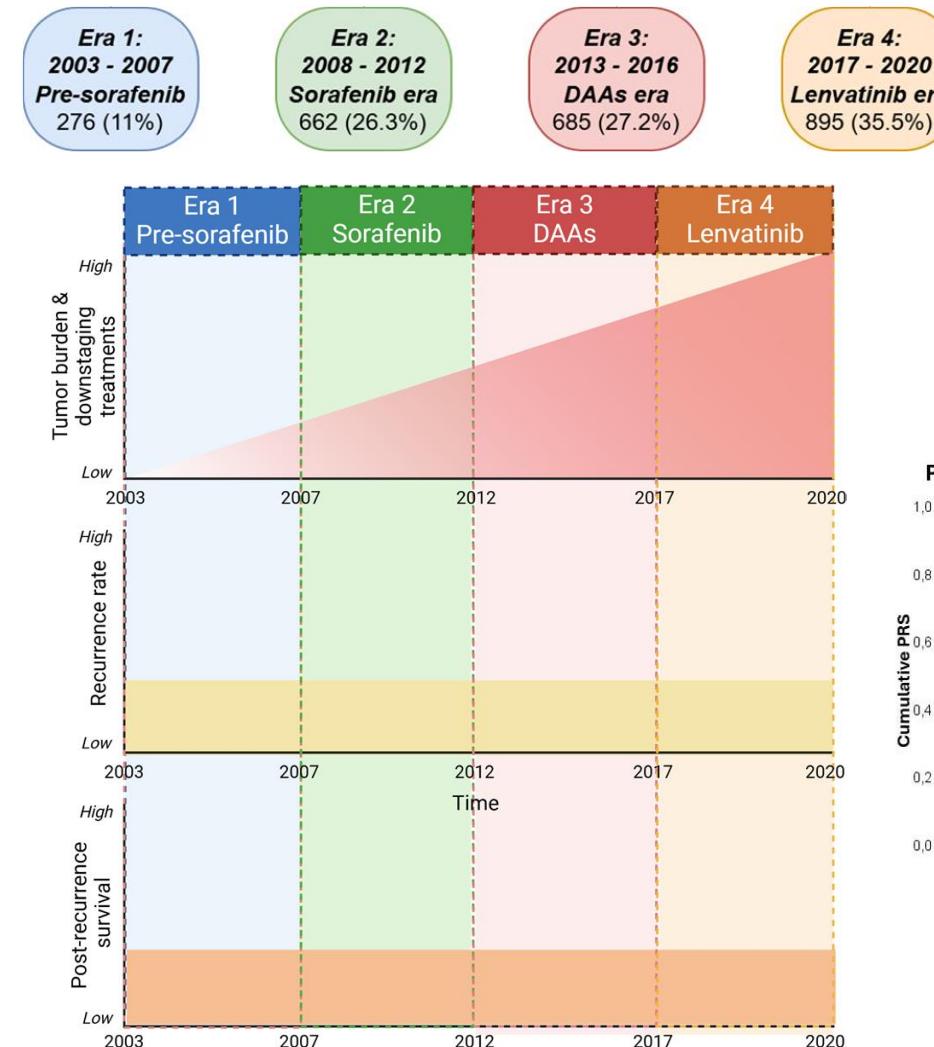
Scientific Registry of Transplant Recipients (SRTRs)
2003 - 2020 : 2518 patients with LT for HCC

At multivariable analysis, only time to recurrence <24 months and G3 HCC were associated with PRS, while recurrence era was not.

Post-recurrence survival after LT for HCC



While PRS after LT for HCC has improved with respect to the early days of inception of transplant oncology, it has not improved during the last 2 decades



There has been an increase of tumor burden and neoadjuvant treatments in later eras, without a significant change in post-transplant recurrence survival

PRS has significantly improved in patients with Milan-IN tumors at LT

LDLT as a model for non-restrictive criteria for LT in HCC

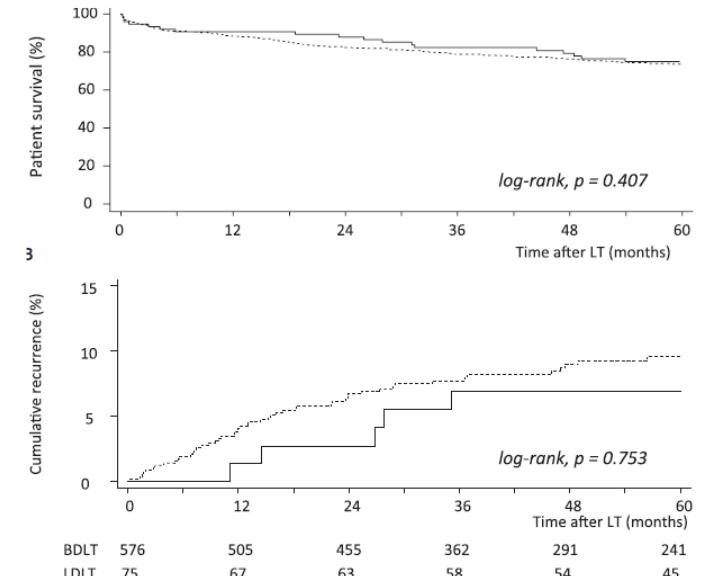
TABLE 5. Risk of HCC Recurrence After Liver Transplantation, Fine and Gray Competing Risks Regression Model (n = 651)

		Univariate Analysis		Multivariate Analysis			
		SHR (95% CI)	P	Model A*		Model B*	
				SHR (95% CI)	P	SHR (95% CI)	P
Age, years	Per 1 year increase	0.98 (0.94;1.01)	0.152	0.97 (0.94;1.01)	0.108	0.98 (0.94;1.01)	0.224
Sex	Male	1.44 (0.62;3.34)	0.395	1.32 (0.52;3.38)	0.559	1.35 (0.54;3.33)	0.521
Underlying liver disease	Viral	1 (reference)		1 (reference)		1 (reference)	
	Alcohol	0.85 (0.48;1.52)	0.590	0.97 (0.51;1.82)	0.917	1.00 (0.52;1.93)	0.992
	Viral + alcohol	1.12 (0.43;2.92)	0.816	0.85 (0.30;2.43)	0.766	1.05 (0.37;3.00)	0.926
	Others	1.47 (0.61;3.51)	0.392	1.41 (0.52;3.82)	0.495	1.67 (0.60;4.61)	0.323
Pre-transplant treatment	Radiofrequency/TACE	1 (reference)		1 (reference)		1 (reference)	
	Surgery/combined	1.24 (0.31;5.01)	0.762	1.02 (0.34;3.03)	0.972	1.22 (0.40;3.71)	0.727
	None	0.97 (0.57;1.66)	0.909	0.88 (0.45;1.70)	0.699	0.90 (0.47;1.73)	0.760
ABO blood group	A	1 (reference)		1 (reference)		1 (reference)	
	AB	1.17 (0.41;3.35)	0.775	0.86 (0.25;2.94)	0.811	0.92 (0.29;2.93)	0.888
	B	0.50 (0.17;1.43)	0.194	0.41 (0.13;1.30)	0.131	0.46 (0.15;1.36)	0.159
	O	0.77 (0.41;1.45)	0.421	0.74 (0.36;1.53)	0.414	0.72 (0.34;1.53)	0.396
Child-Pugh class	AB	1 (reference)		1 (reference)		1 (reference)	
	C	1.19 (0.61;2.32)	0.613	1.07 (0.43;2.66)	0.888	1.14 (0.48;2.74)	0.764
MELD score at listing	Per 1 point increase	1.00 (0.96;1.05)	0.911	—	—	—	—
	<15	1 (reference)		1 (reference)		1 (reference)	
	15-25	1.25 (0.65;2.41)	0.508	1.11 (0.47;2.59)	0.817	1.09 (0.47;2.52)	0.837
	≥25	1.68 (0.64;4.40)	0.294	1.45 (0.46;4.59)	0.527	1.57 (0.53;4.64)	0.413
Waiting time on list, months	Per 1 month increase	0.99 (0.94;1.04)	0.780	1.00 (0.96;1.04)	0.972	1.00 (0.95;1.05)	0.969
Graft type (BDLT /LDLT)	BDLT group	1 (reference)		1 (reference)		1 (reference)	
	LDLT group	0.91 (0.42;1.96)	0.806	1.64 (0.50;5.34)	0.415	1.50 (0.45;4.92)	0.507
Donor age	≥60 y	1.31 (0.74;2.34)	0.356	1.15 (0.61;2.16)	0.661	1.33 (0.70;2.50)	0.379
Cold ischemia time, hours	Per 1 hour increase	0.99 (0.92;1.06)	0.768	0.97 (0.86;1.08)	0.560	0.96 (0.86;1.07)	0.492
Transfusion	Per 1 unit increase	1.01 (0.98;1.04)	0.501	1.01 (0.97;1.05)	0.589	1.01 (0.97;1.05)	0.594
Microscopic vascular invasion		2.61 (1.57;4.33)	<0.001	—	—	—	—
Macroscopic vascular invasion		3.45 (1.94;6.13)	<0.001	2.21 (1.21;4.06)	0.010	2.26 (1.26;4.08)	0.007
Satellite nodules		2.29 (1.38;3.82)	0.001	1.36 (0.77;2.40)	0.292	1.31 (0.72;2.38)	0.384
Milan criteria (explanted liver)	Out	3.52 (2.03;6.10)	<0.001	2.81 (1.54;5.12)	0.001	—	—
AFP model score (explanted liver)	>2	3.54 (2.10;5.97)	<0.001	—		2.71 (1.48;4.95)	0.001
Edmondson grade I-II vs. III-IV	III-IV	2.21 (1.26;3.86)	0.006	1.70 (0.93;3.10)	0.086	1.69 (0.93;3.10)	0.087

AFP indicates alpha-fetoprotein; BDLT, brain-dead donor liver transplantation; CI, confidence interval; HR, hazard ratio; LDLT, living donor liver transplantation; MELD, Model for end stage liver disease; SHR, sub-hazard ratio; TACE, transarterial chemoembolization.

Bolded results are significant at the $P < 0.05$ level.

*Two alternative multivariate models were built to prevent collinearity between Milan and AFP model score, entering (A) Milan criteria or (B) AFP model score.

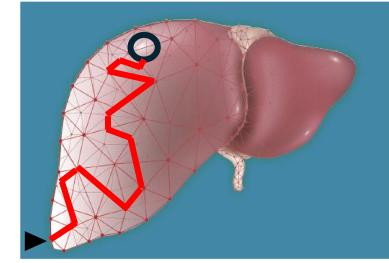
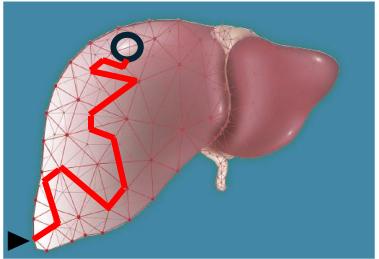


BDLT drop-out rate: 20.7%
LDLT drop-out: none (0%)

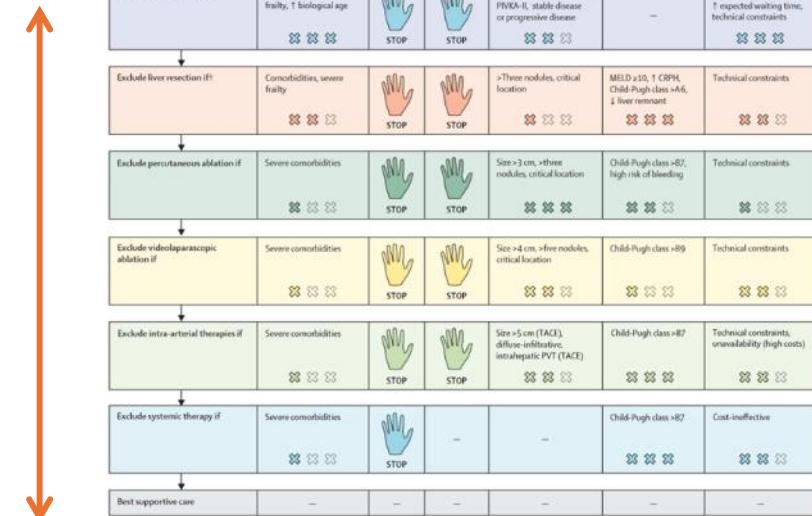
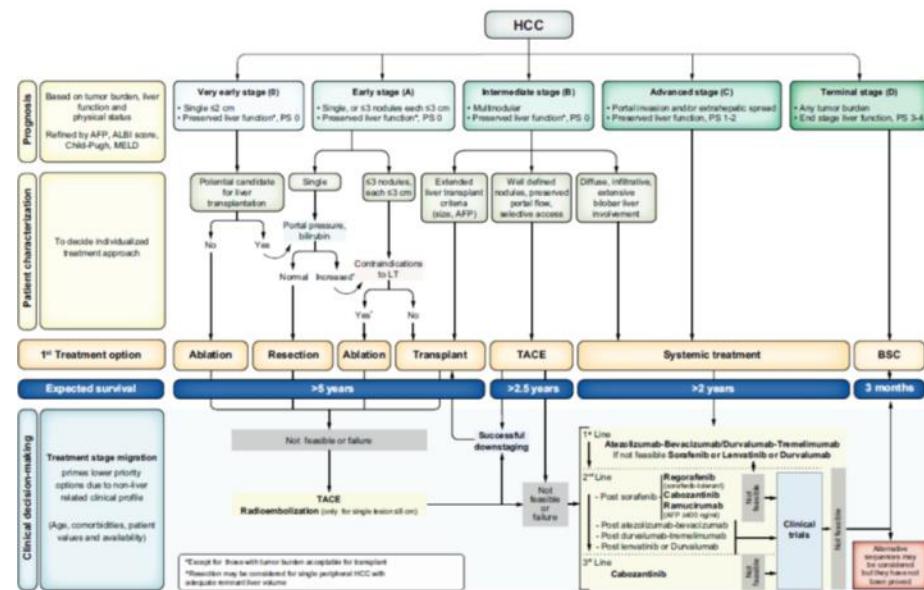
Graft type was not associated with risk of recurrence

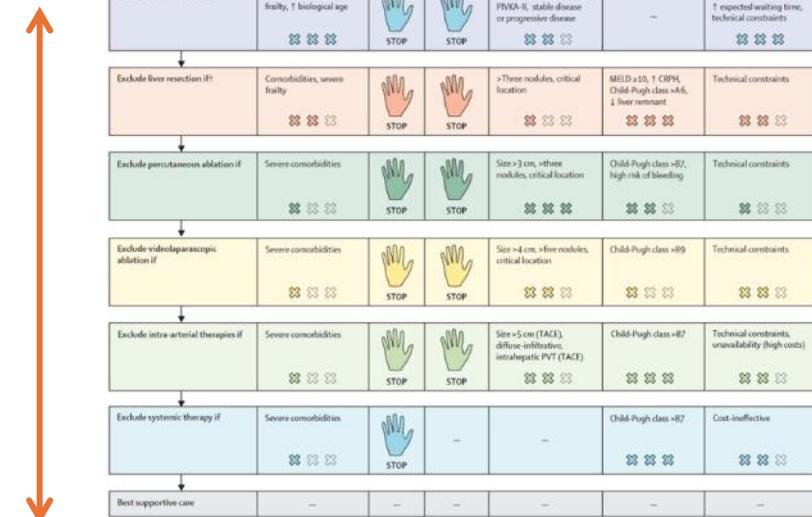
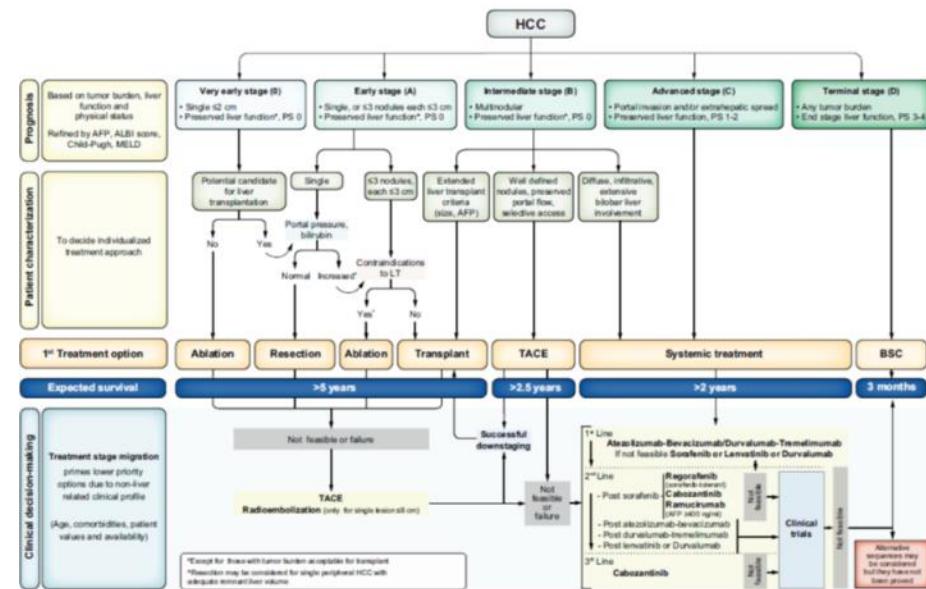
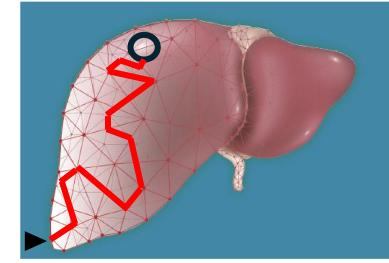
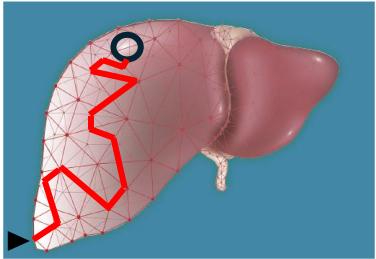
Independent predictors of recurrence were:
in Model A: macroscopic vascular invasion [HR 2.21],
and tumor exceeding the Milan criteria [HR 2.81]; (ii)
in Model B: macroscopic vascular invasion [HR 2.26]
and AFP model score >2 [HR 2.71]





Thanks to technologic advancements, big data analysis,
and powerful networks we are entering an
Era of Translation
in modelling outcome predictions and decision-making

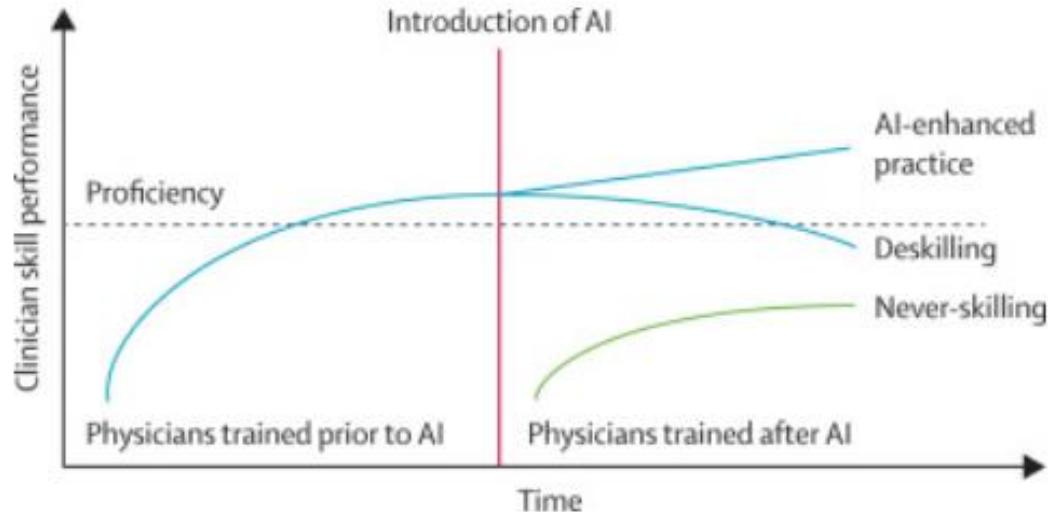




Domain-specific excellence is emerging, with vast potential for translational progress. In an era in which big, deep, and longitudinal data are available, **relying on a simple, singular or binary measure to define risk is simplistic**. If all dimensions of data were integrated, just think how much better we could identify risk group in an era in which treatments are develop and people are aware.

Preserving clinical skills in the age of AI assistance

Tyler M Berzin ^a  · Eric J Topol ^b



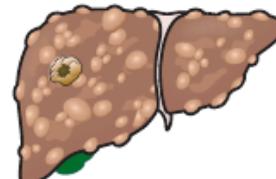
As A.I. assumes a growing role in clinical practice, concerns is mounting that off-load clinical tasks and reasoning will lead to **loss of skills (deskilling)** adopting errors or bias from A.I. (mis-skilling), or failure to achieve competence (never skilling)

Gain in translation

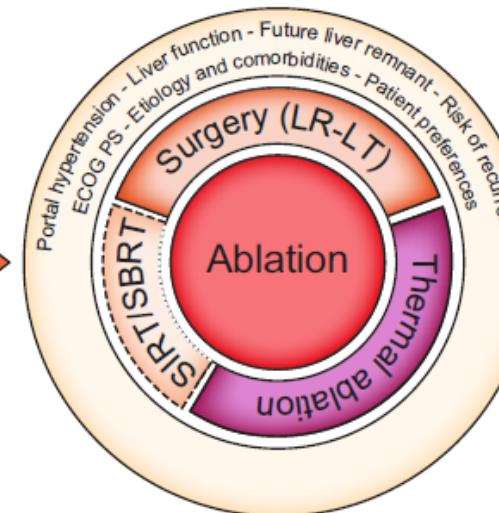
Gain in translation

The Translation of Transplant indication in HCC

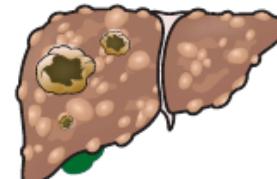
Small burden of disease



BCLC stage 0-A-B



Large burden of disease



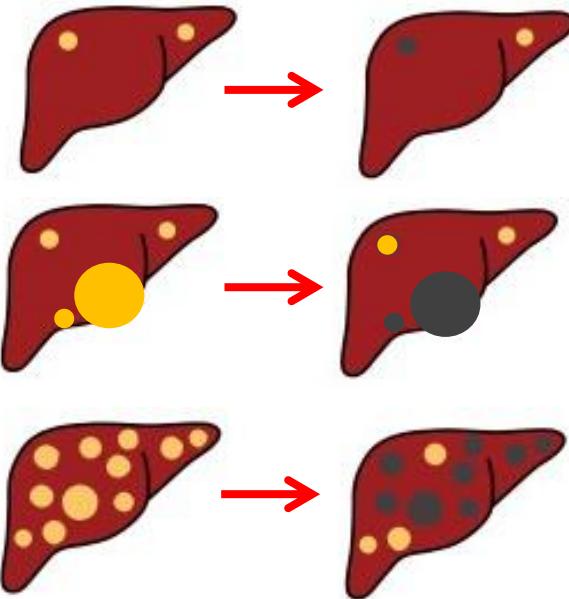
BCLC stage B-C

Intra-arterial therapy

Downstaging - Downsizing

Systemic therapy

EASL Clinical Practice Guidelines J.Hepatol 2025



Neoadjuvant («bridge»)

Downstaging

Conversion

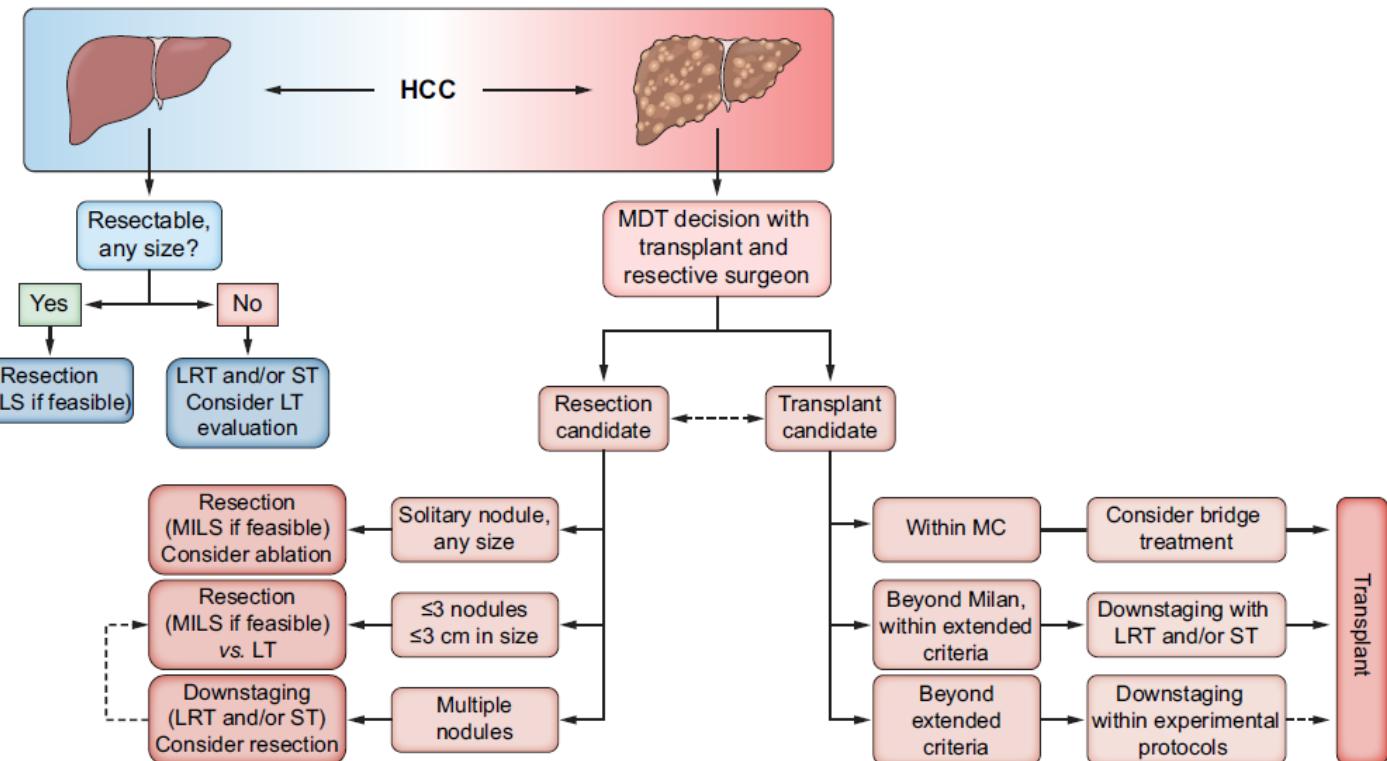
Already within Milan

e.g. within UNOS-DS Within Milan

All comers Within Milan

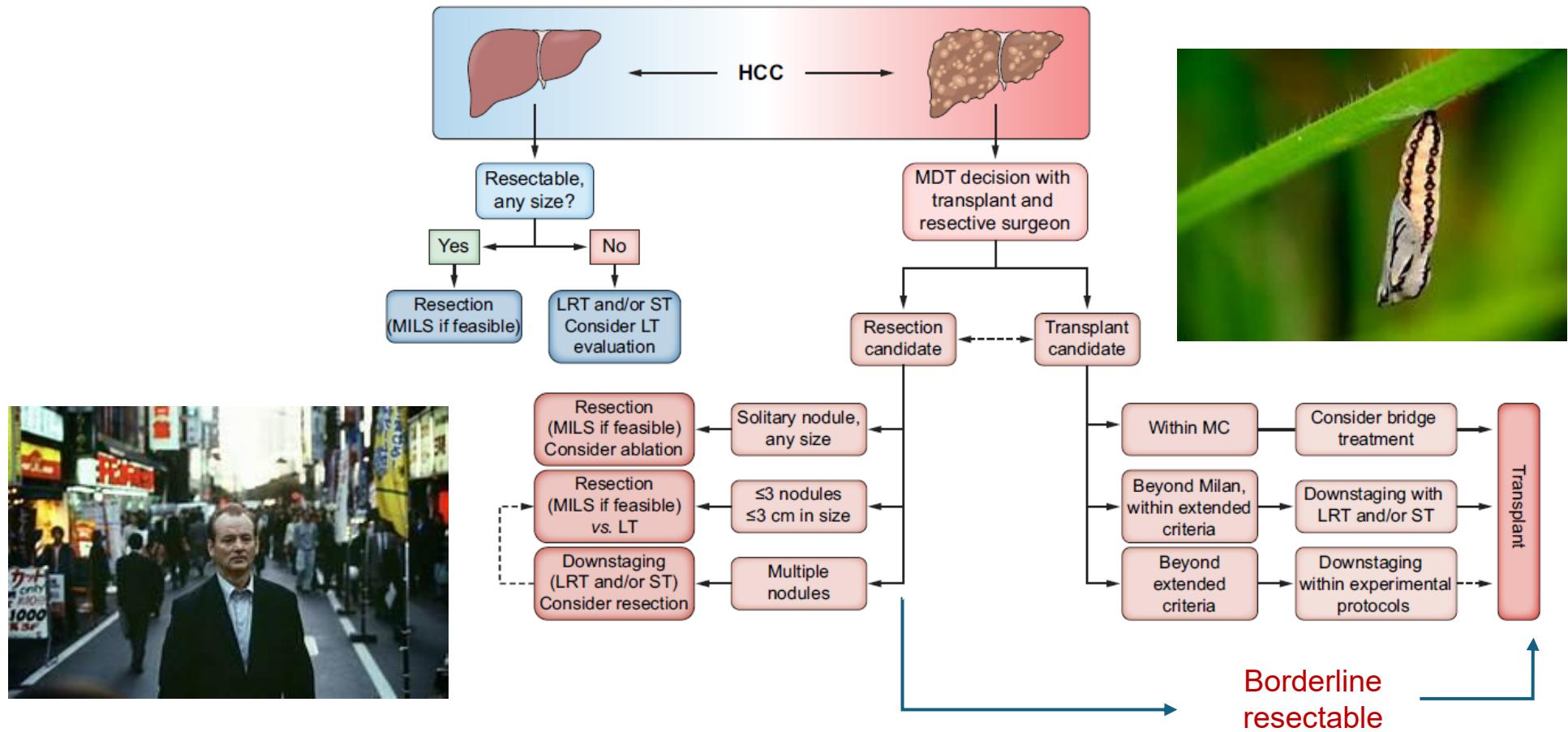
Translation of borderline resectable, ALPPS, staged hepatectomies for HCC?

- Heterogeneities in defining surgical feasibility and surgical futility influence indication, patient selection and outcome



Translation of borderline resectable, ALPPS, staged hepatectomies for HCC?

- Heterogeneities in defining surgical feasibility and surgical futility influence indication, patient selection and outcome



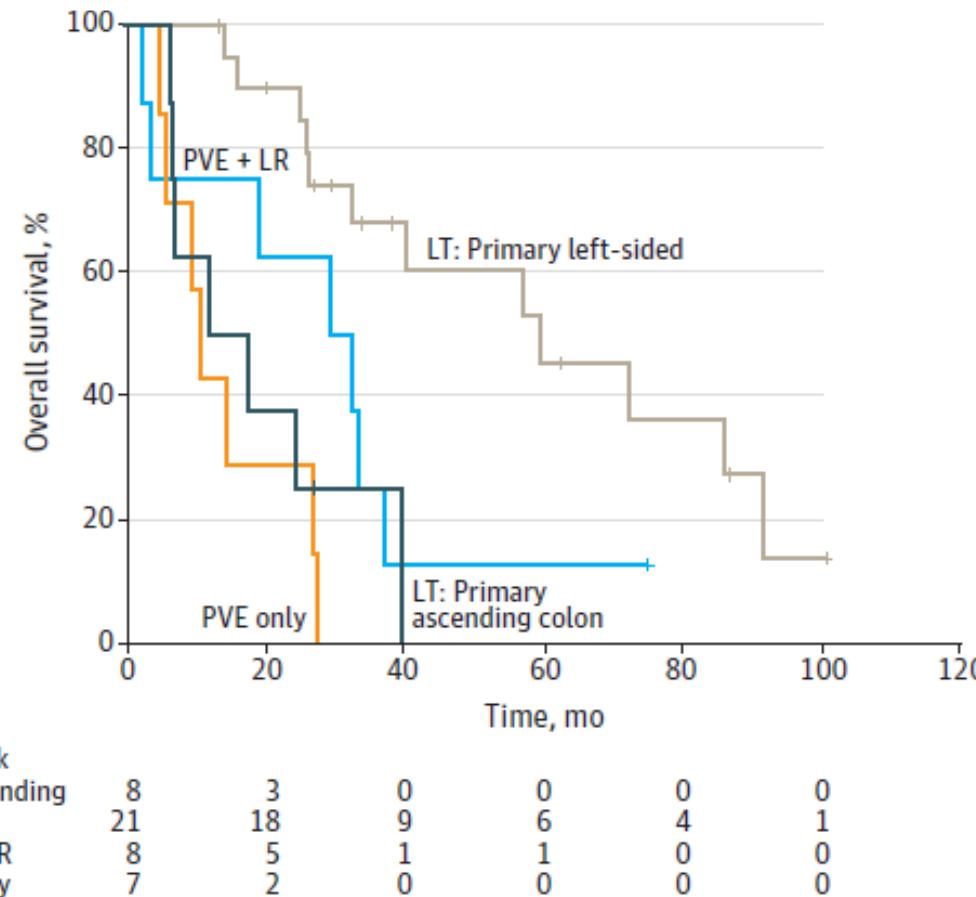
LT vs. PVE followed by liver resection (PVE+LR)

50 LT (2006-2019) at Oslo University compared with a retrospective cohort of 53 PVE+LR (2006-2015)

- Similar selection criteria
- **Different tumor load at inception**

High tumor load:

25.8% in the PVE+LR group: 58.0% in the LT group

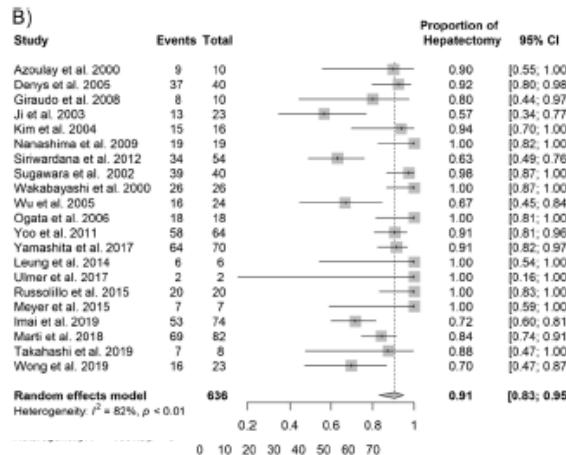


- ✓ LT yields a longer overall survival among selected patients with advanced CRLM with high tumor burden with respect to PVE followed by liver resection
- Right-sided primary tumor is a distinct negative prognostic factor (among other factors are more pN+)
- Patients with <9 liver metastases <5.5 cm in diameter, may obtain long OS also with LR following the PVE
- Patients with high liver tumor load benefit from LT even if they are resectable
- Patients who do not respond to PVE may be evaluated for LT.

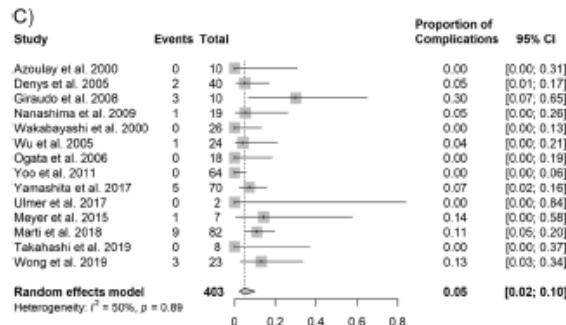
The Transition of complex liver resection to transplantation

Systematic reviews of future liver remnant percent hypertrophy, proportion undergoing hepatectomy and proportion with major complications following PVE, ALPPS, and RL

Proportion undergoing hepatectomy



Proportion with major complications



PVE: 91% completed with 5% DCC > 3

ALPPS Versus Portal Vein Embolization for Hepatitis-related Hepatocellular Carcinoma

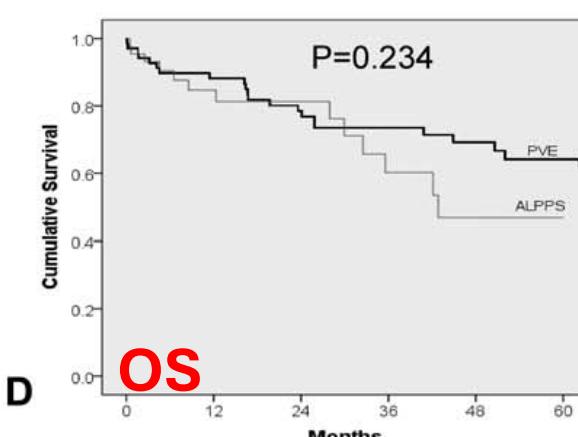
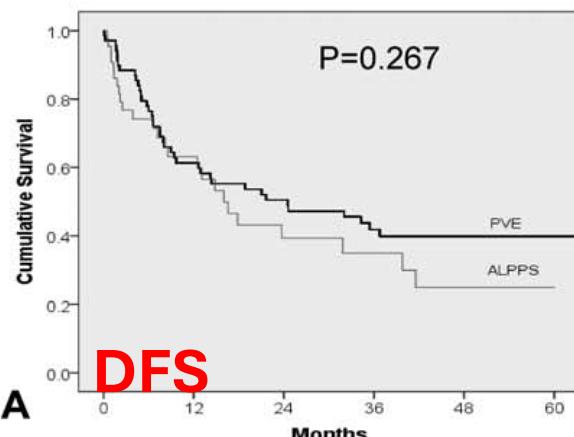
A Changing Paradigm in Modulation of Future Liver Remnant Before Major Hepatectomy

46 ALPPS vs 102 PVE

Cirrhosis 50%

Median size: 8.5 cm

Median n: 1 (1-3)



64.1%

46.8%

Failure rate:

- ALPPS: 2.2%
- PVE: 32.3%

Morbidity:

- ALPPS: 30.4%
- PVE: 20.7%

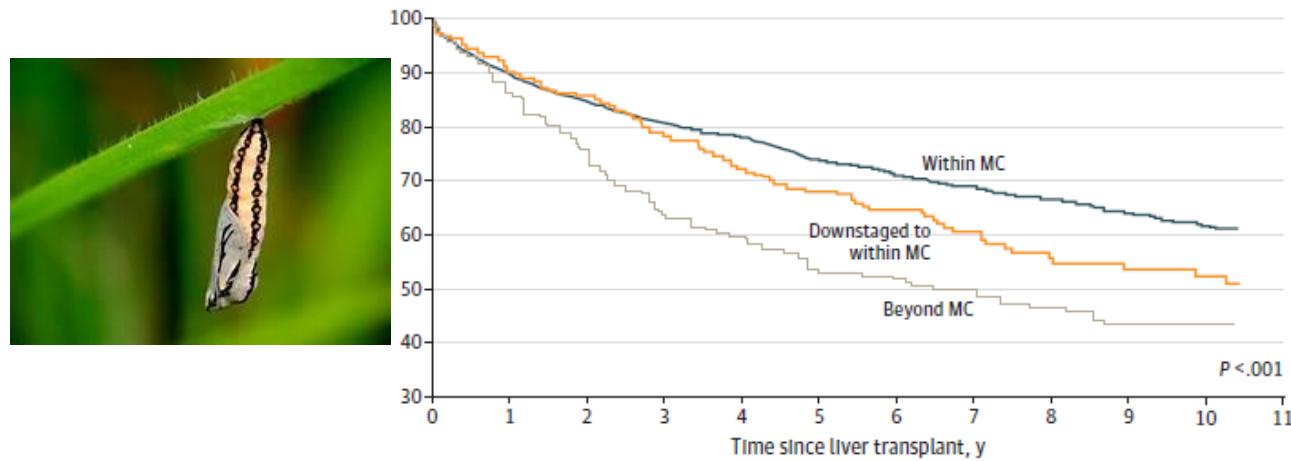
Mortality:

- ALPPS: 6.5%
- PVE: 5.8%

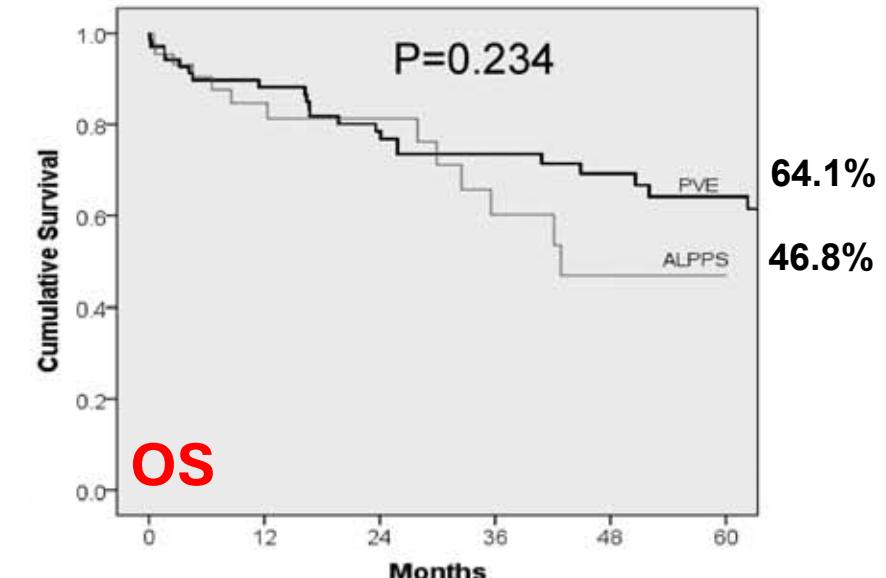
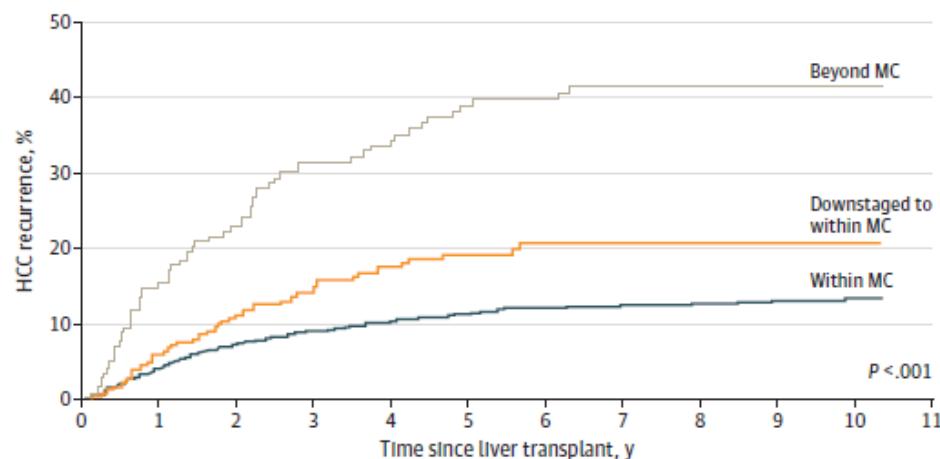


The Translation of complex resective liver surgery to the Transplant perspective

A Overall survival among patients with HCC after liver transplant by subgroup

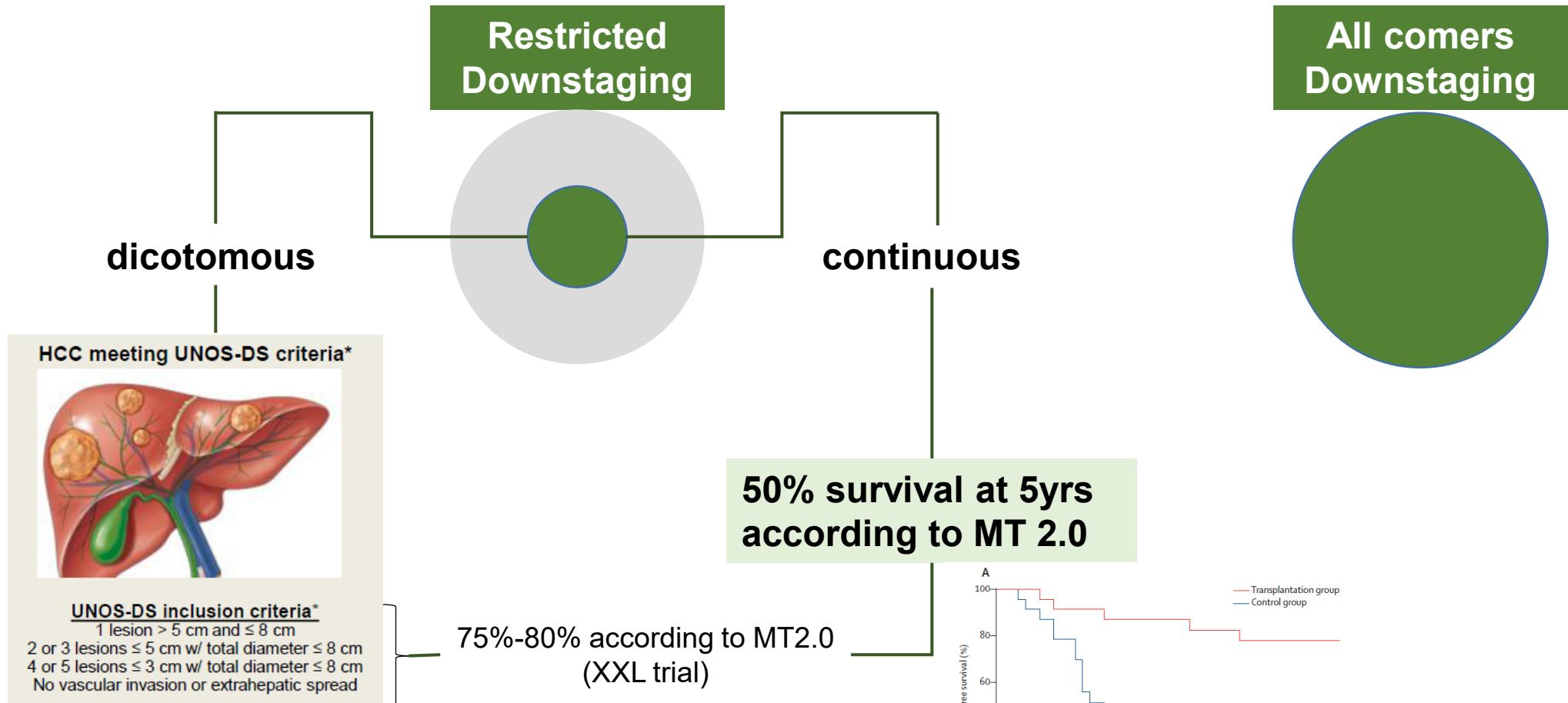


B Overall recurrence of HCC after liver transplant by subgroup

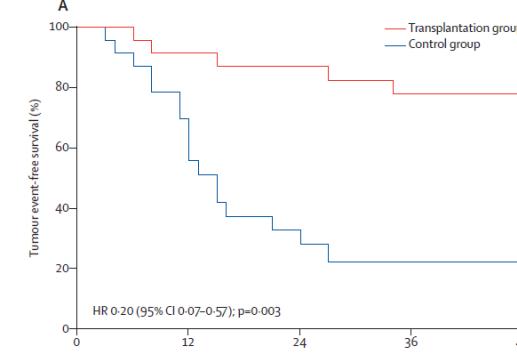


No. at risk	Within MC	Downstaged to within MC	Beyond MC
Within MC	2122	341	182
Downstaged to within MC	341	280	141
Beyond MC	182	141	119

The Translation of Downstaging boundaries for LT candidates with HCC

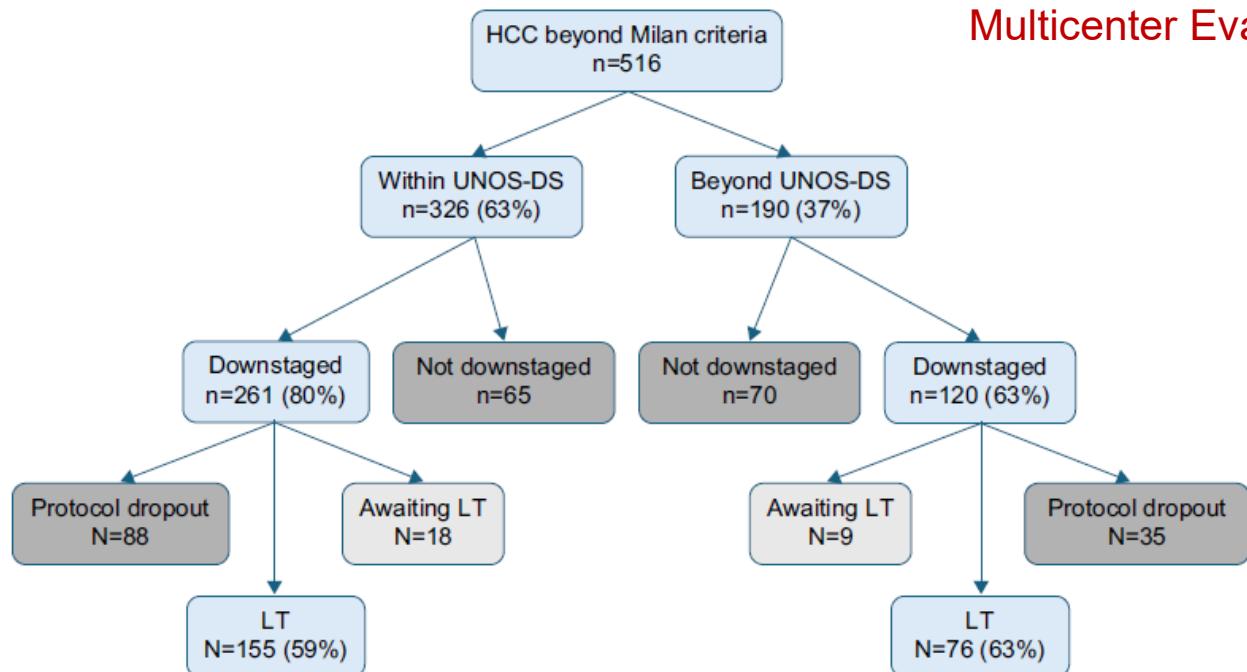


Mehta N et al. Gastroenterology 2021



Mazzaferro V et Al. Lancet Oncology 2020

Multicenter Evaluation of Reduction in Tumor Size before Liver Transplantation (MERITS-LT) consortium



Predictors of successful downstaging

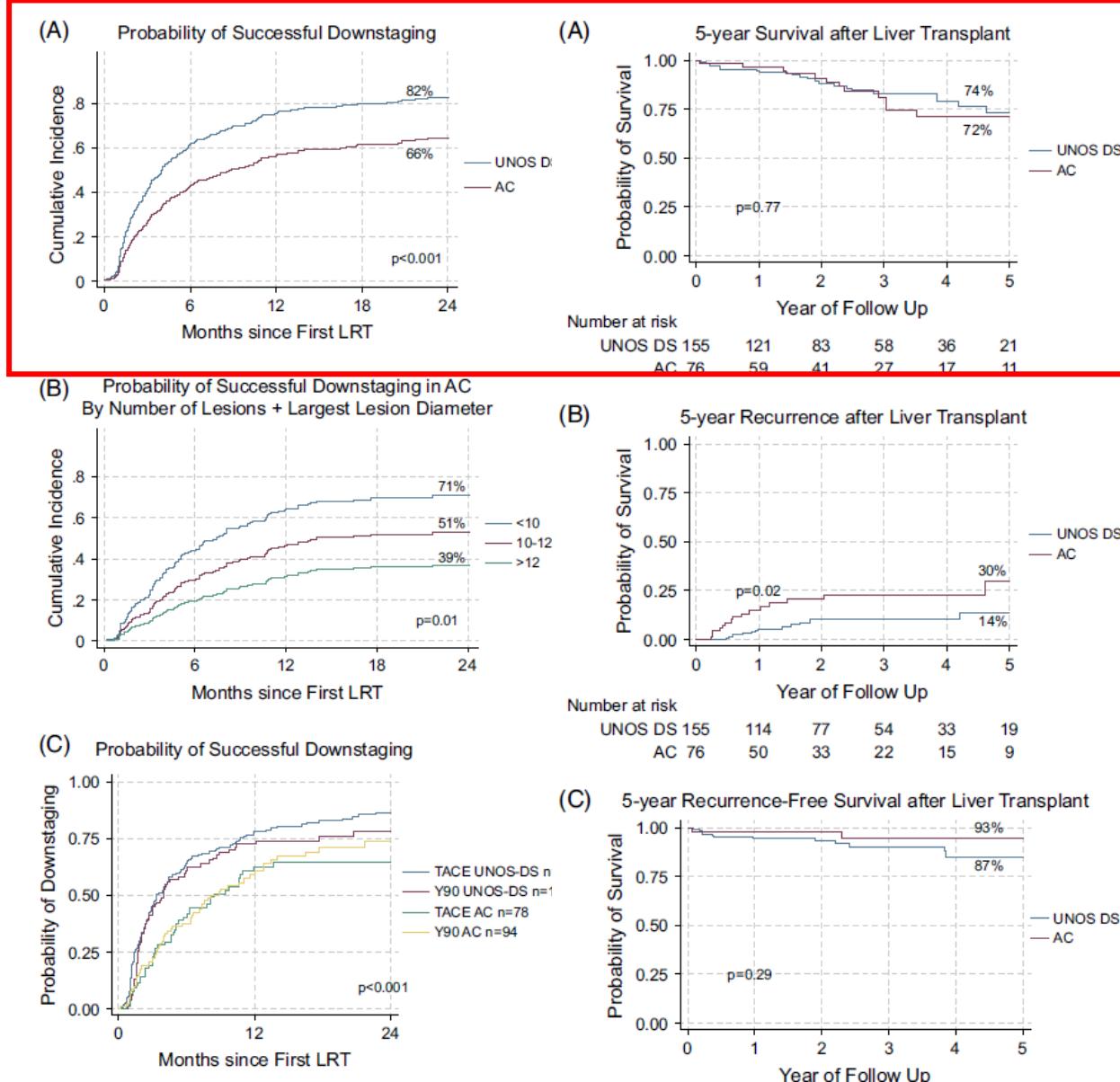
Multivariable analysis

No. of lesions + largest lesion diameter (per unit)	0.84 (0.79–0.89)	<0.01
MASLD as Etiology (vs. hepatitis C)	0.72 (0.52–0.99)	0.048

Predictors of inferior 5-year post-LT survival

Multivariable analysis

Age (per y)	1.08 (1.02–1.14)	0.01
MASLD as etiology (vs. hepatitis C)	3.01 (1.08–8.39)	0.04
Explant microvascular invasion	3.77 (1.80–7.92)	<0.01



Despite higher HCC recurrence and lower ITT survival in AC, post-LT survival was comparable between UNOS-DS and all comers (AC), therefore LT after DS is feasible in AC. Defining an upper limit in tumor burden however is necessary

Breakthrough innovation in HCC treatment

From Molecular based treatment

Sharp trial: sorafenib vs. placebo

Outcome	Sorafenib (N=299)	Placebo (N=303)	Hazard Ratio (95% CI)	P Value
Overall survival (mo)			0.69 (0.55–0.87)	<0.001
Median	10.7	7.9		
95% CI	9.4–13.3	6.8–9.1		
1-yr survival rate (%)	44	33		0.009
Time to symptomatic progression (mo)†			1.08 (0.88–1.31)	0.77
Median	4.1	4.9		
95% CI	3.5–4.8	4.2–6.3		
Time to radiologic progression (mo)			0.58 (0.45–0.74)	<0.001
Median	5.5	2.8		
95% CI	4.1–6.9	2.7–3.9		
Level of response (%)‡				
Complete	0	0		NA
Partial	2	1		0.05
Stable disease	71	67		0.17
Disease-control rate (%)	43	32		0.002

To Immunotherapy based treatment

IMbrave150 trial: Atezo+Beva vs. sorafenib

Atezolizumab plus bevacizumab (n = 326)	Sorafenib (n = 159)
Objective response, n (%) [95% CI]	97 (30) [25-35]
Complete response, n (%)	25 (8)
Partial response, n (%)	72 (22)
Stable disease, n (%)	144 (44)
Disease control rate, n (%)	241 (74)
Progressive disease, n (%)	63 (19)
Patients with ongoing response, n (%)	54 (56)
Duration of response, median (95% CI), months*	18.1 (14.6-NE)
Range, months	2.5-25.6†

Cheng et al, J. Hepatol 2022

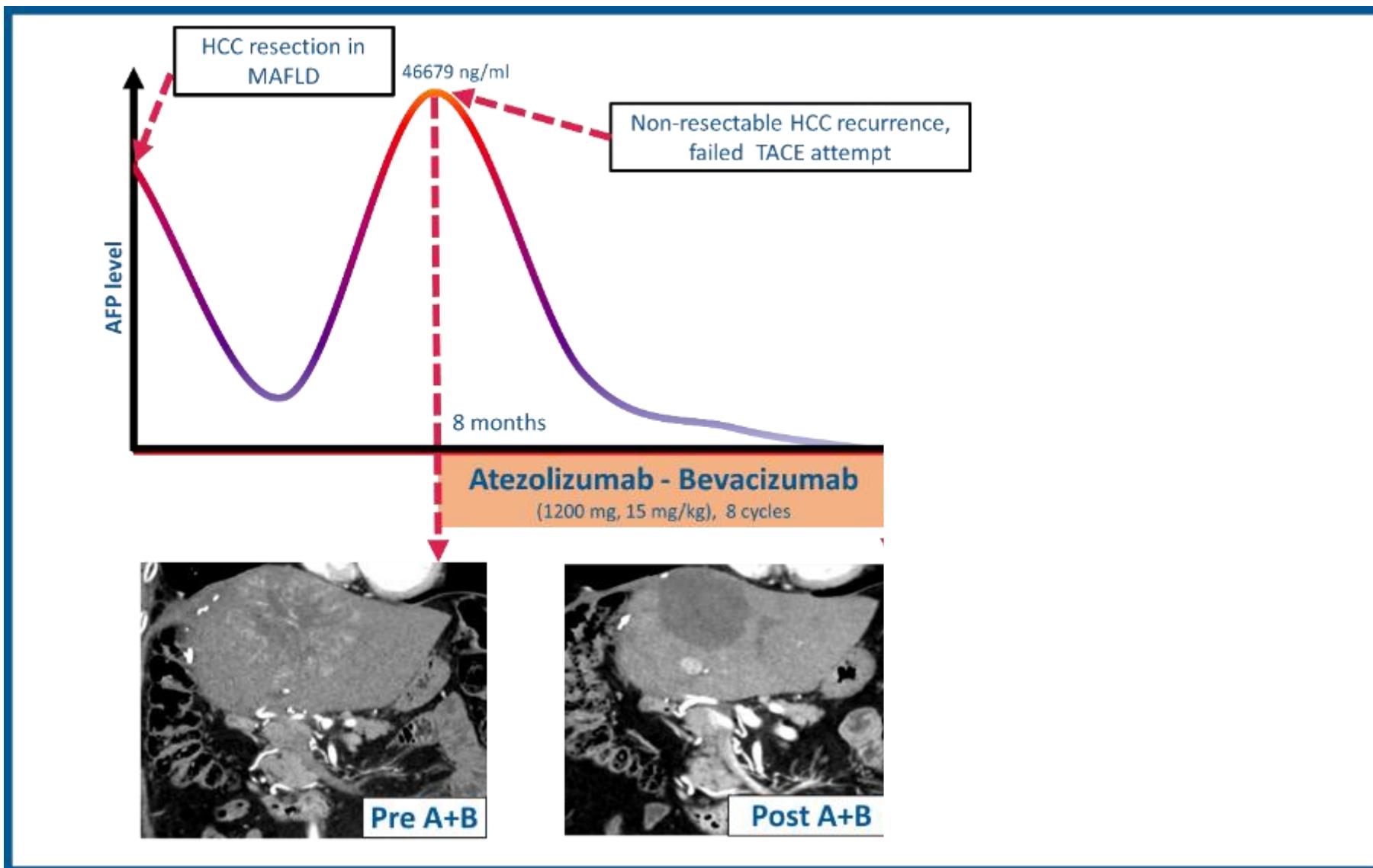
3-yr survival rates < 20%,
DCR<50%, no CR

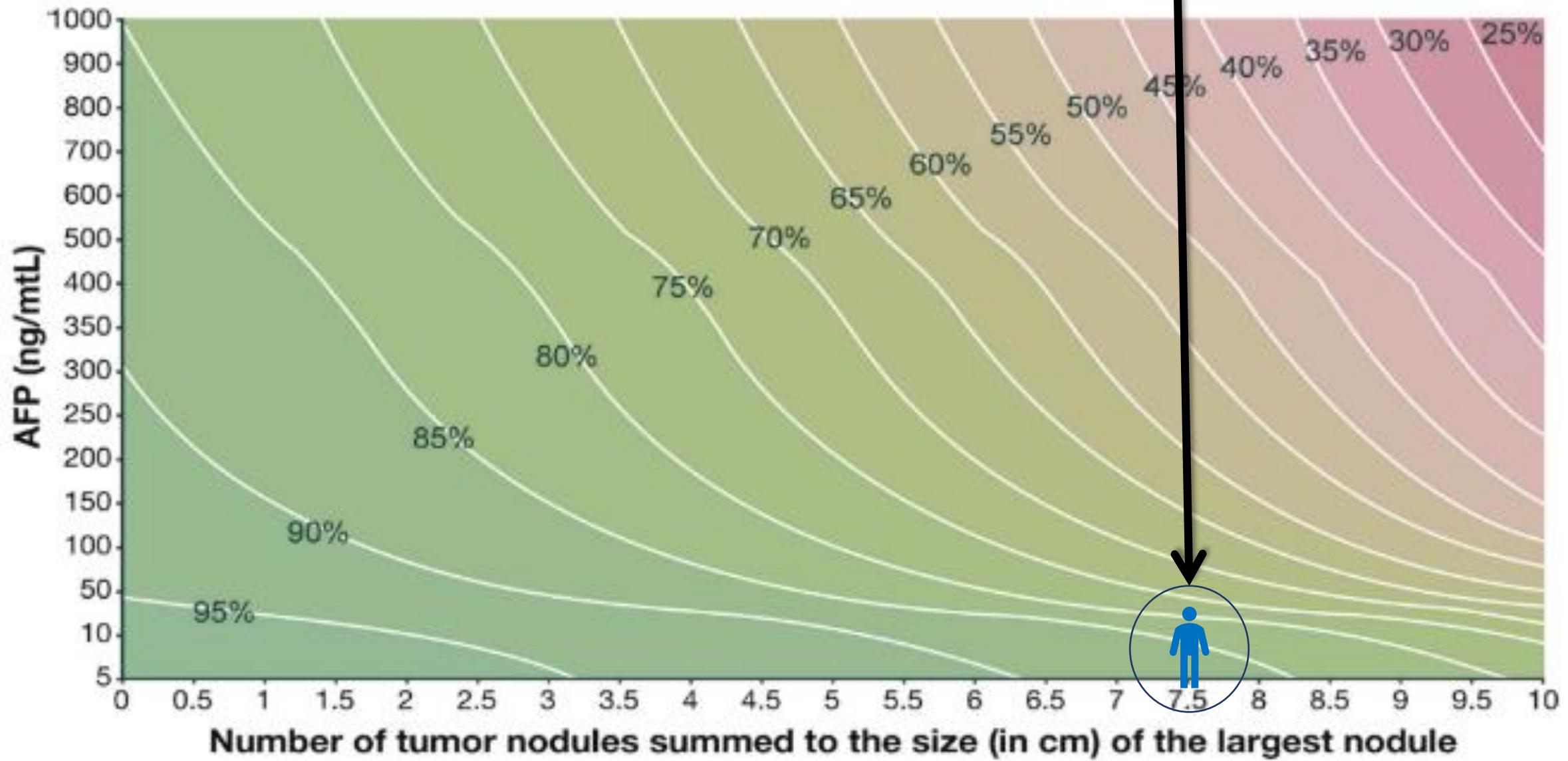
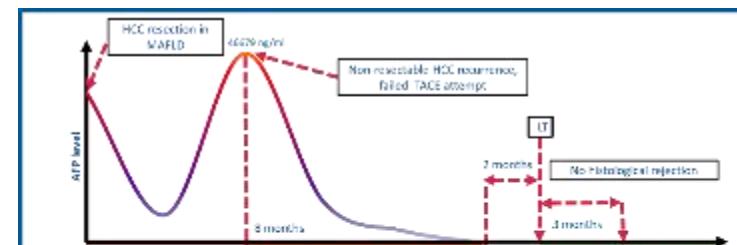
4-yr survival rates 30%,
DCR 74%, CR 8%

If immunotherapy produces deep and durable response

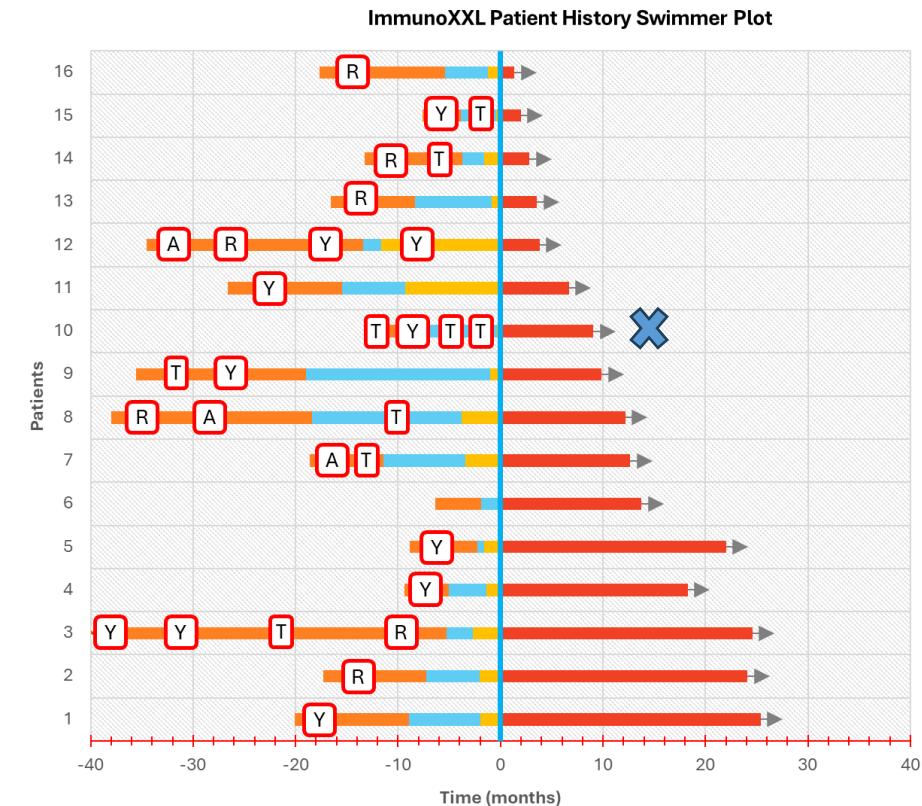
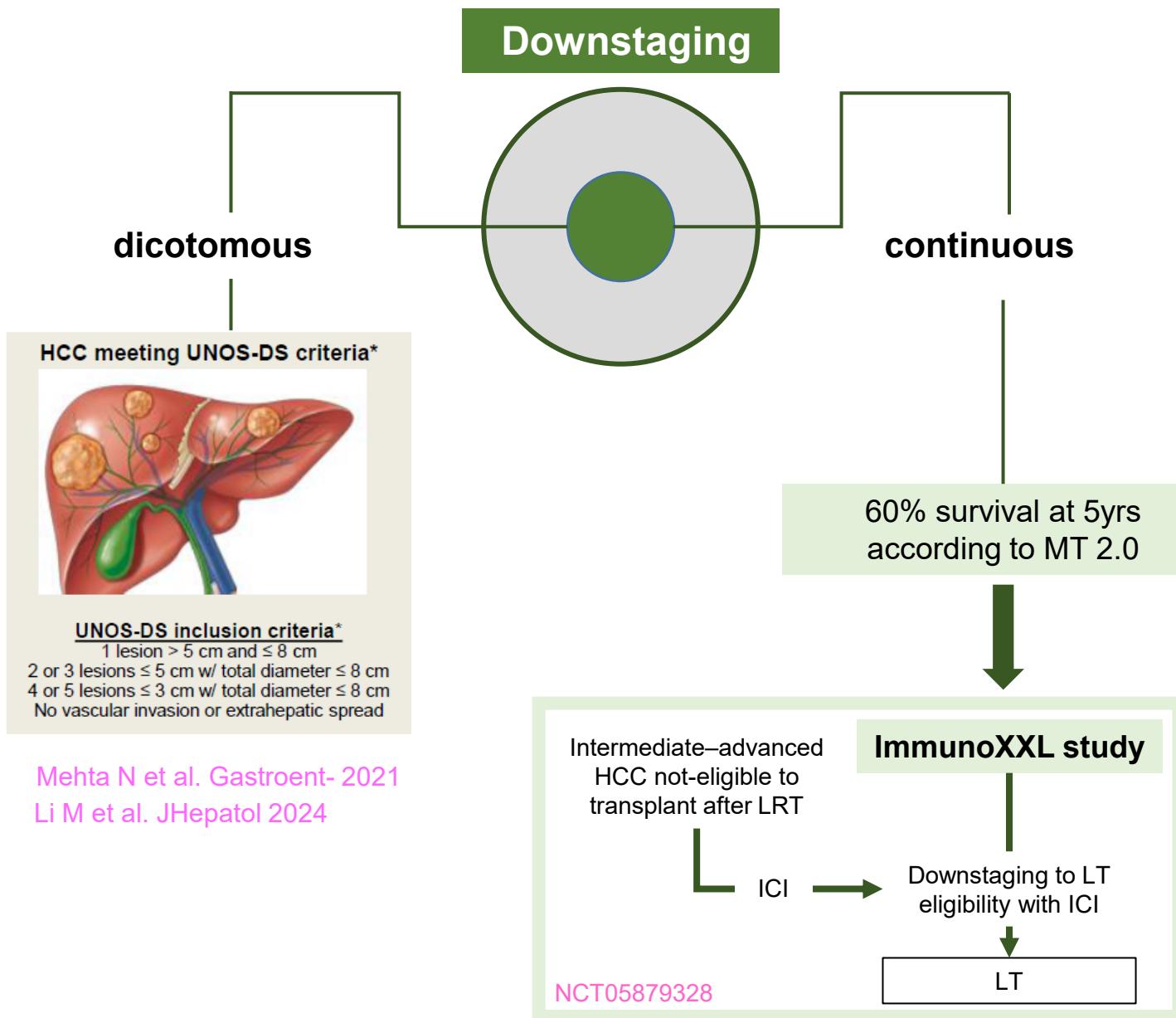


Why not offer liver transplantation and include immunotherapy in neoadjuvant protocols?



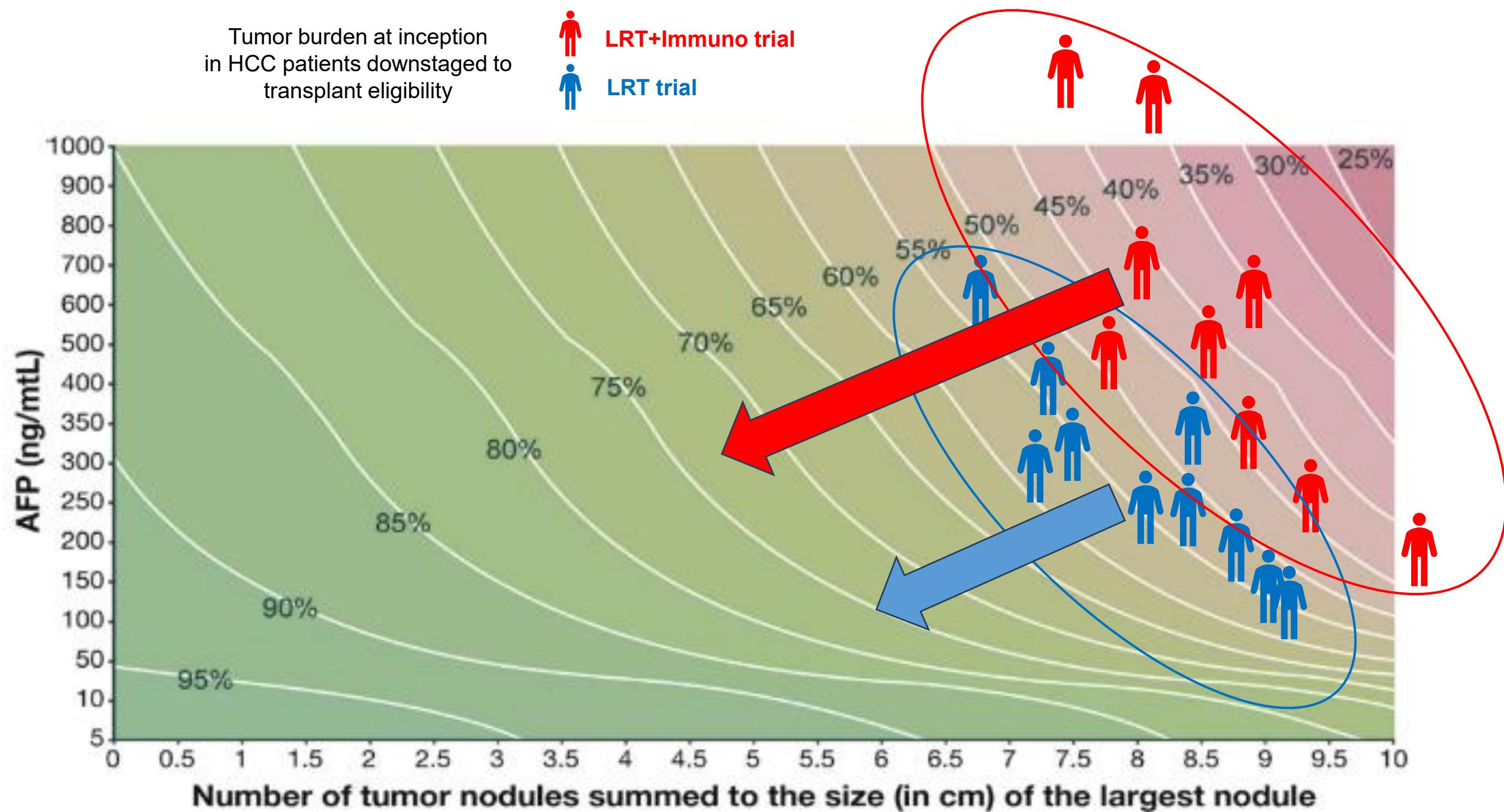


The Translation of Downstaging boundaries for LT candidates with HCC



Tumor burden at inception
in HCC patients downstaged to
transplant eligibility

 **LRT+Immuno trial**
 **LRT trial**



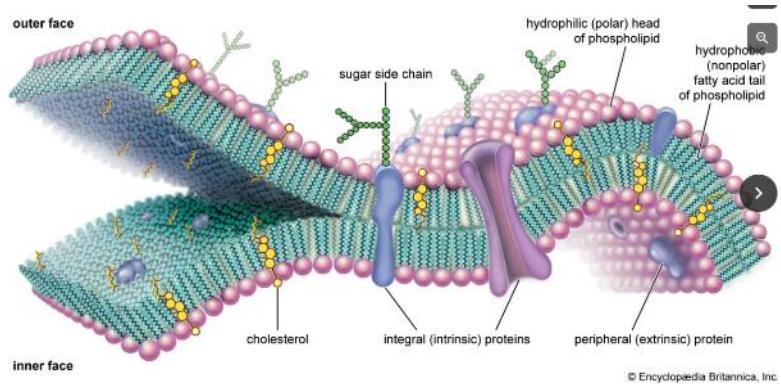
Tumor burden at inception
in HCC patients downstaged to
transplant eligibility

 **LRT+Immuno**
 **LRT only**



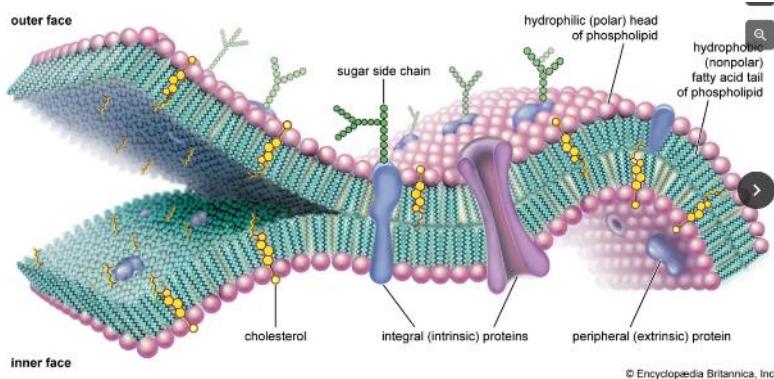
The concept of **"treatable tumor regression"**
commonly referred to as therapeutic
conversion - recognizes that profound tumor
regression does not imply a return to an
earlier baseline stage but creates a distinct
clinical state requiring its own framework.

In conclusion,

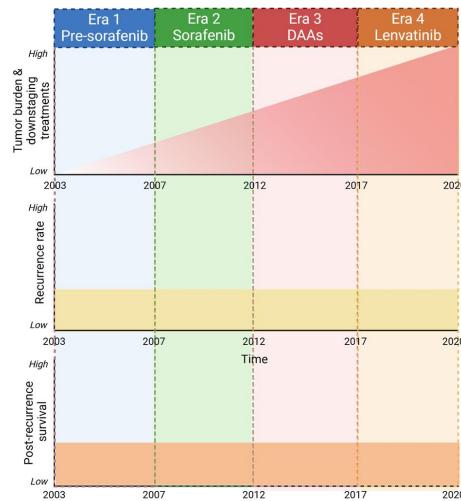


Barriers are essential to life

In conclusion,

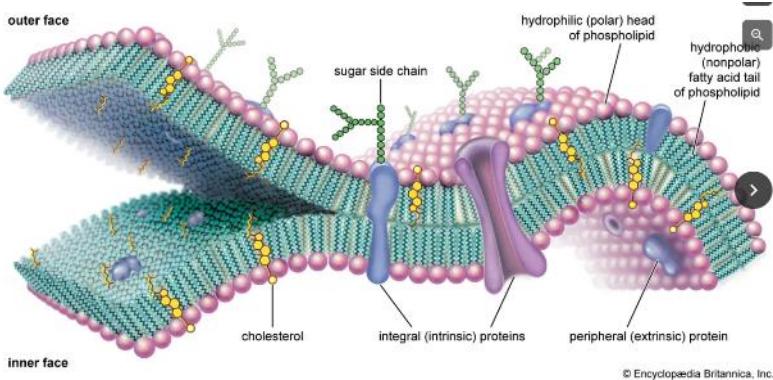


Barriers are essential to life

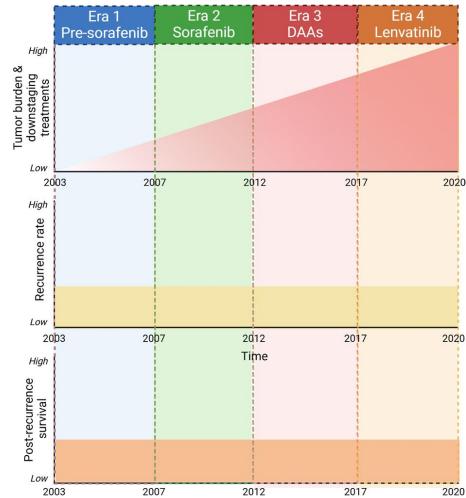


Tumor burden is a barrier that can be managed with non-transplant means

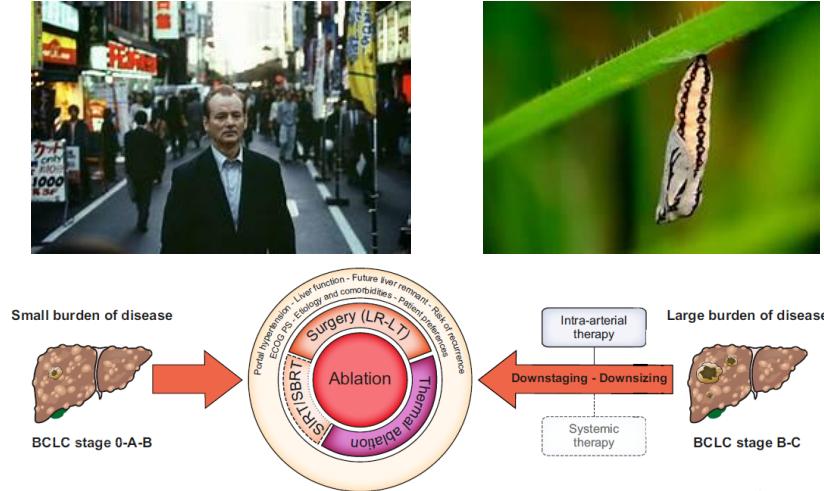
In conclusion,



Barriers are essential to life

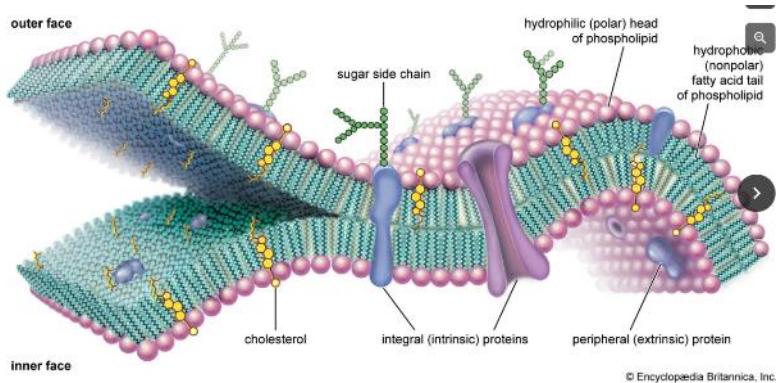


Tumor burden is a barrier that can be managed with non-transplant means

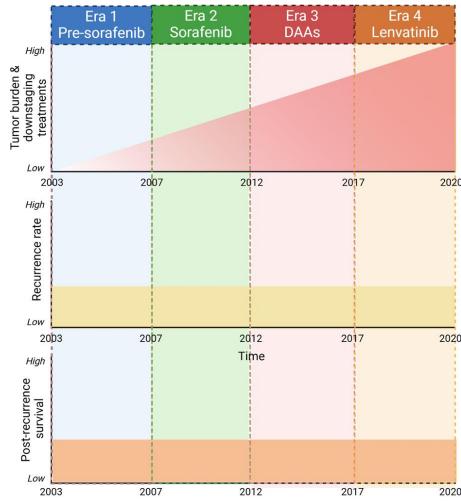


We are entering an **era of Translation** in outcome predictions and decision-making

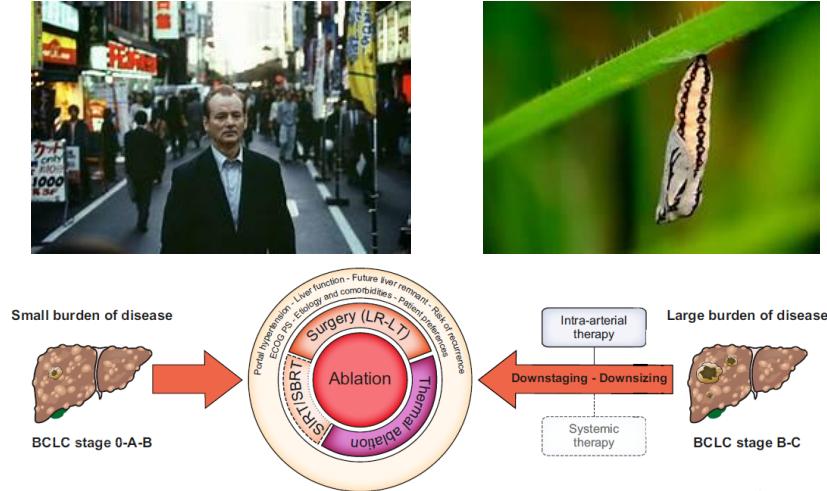
In conclusion,



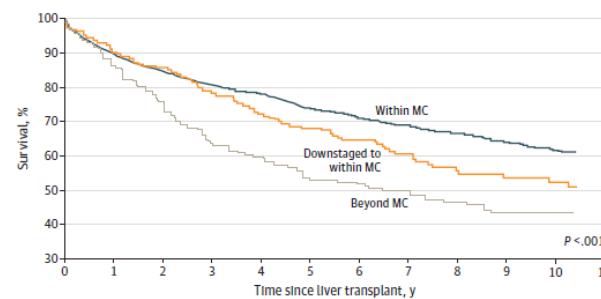
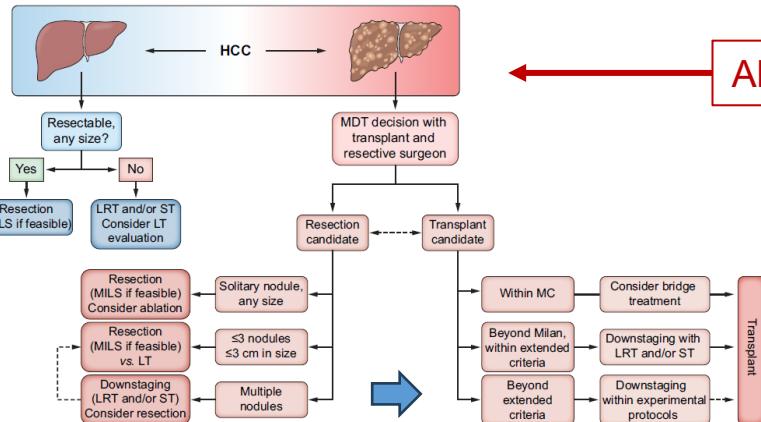
Barriers are essential to life



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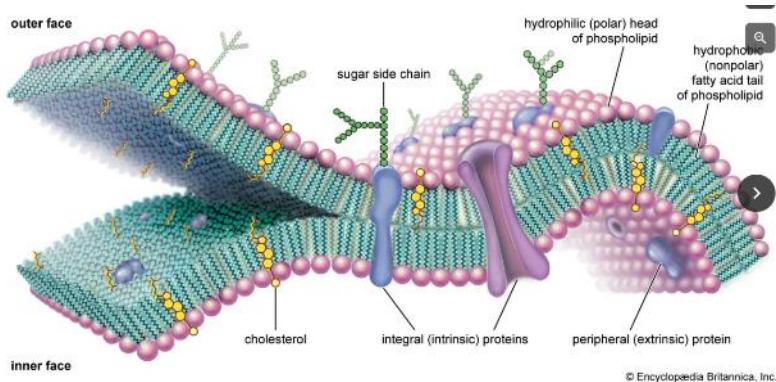
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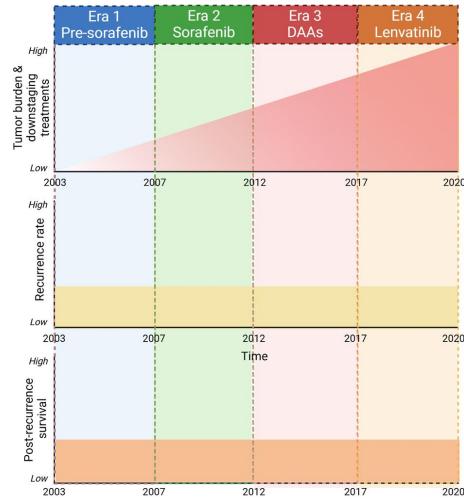
There is an ongoing translation of indications within surgical HCC

There is an ongoing translation to transplant from non surgical HCC

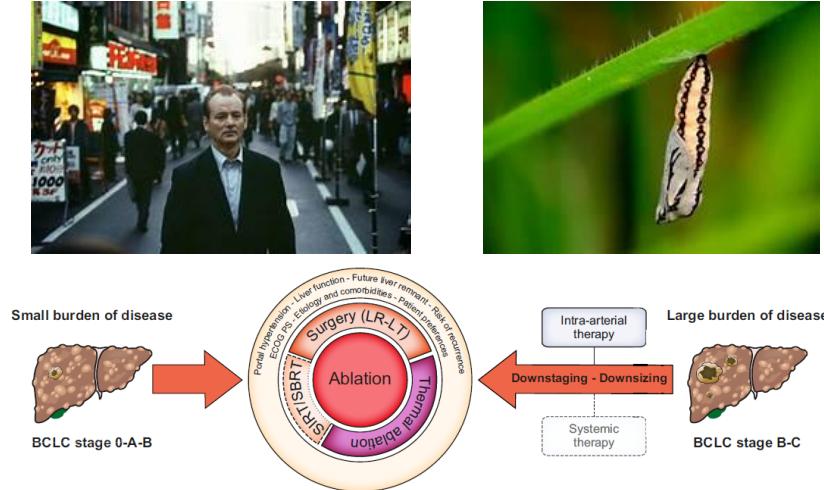
In conclusion,



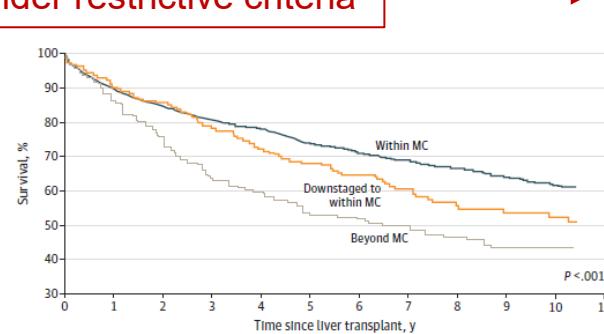
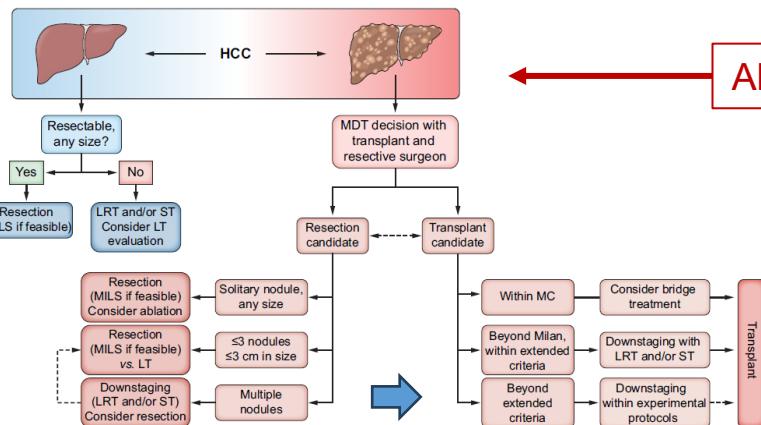
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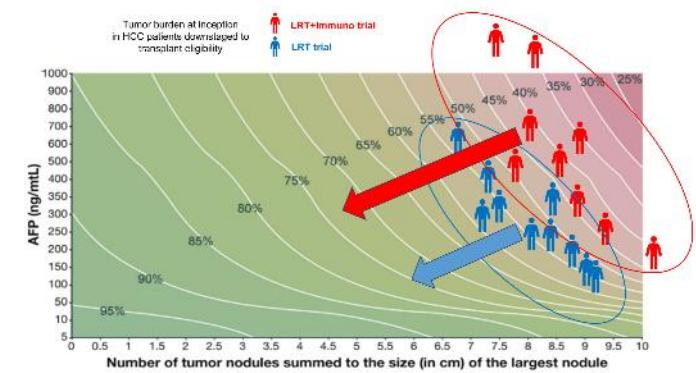


We are entering an **era of Translation** in outcome predictions and decision-making

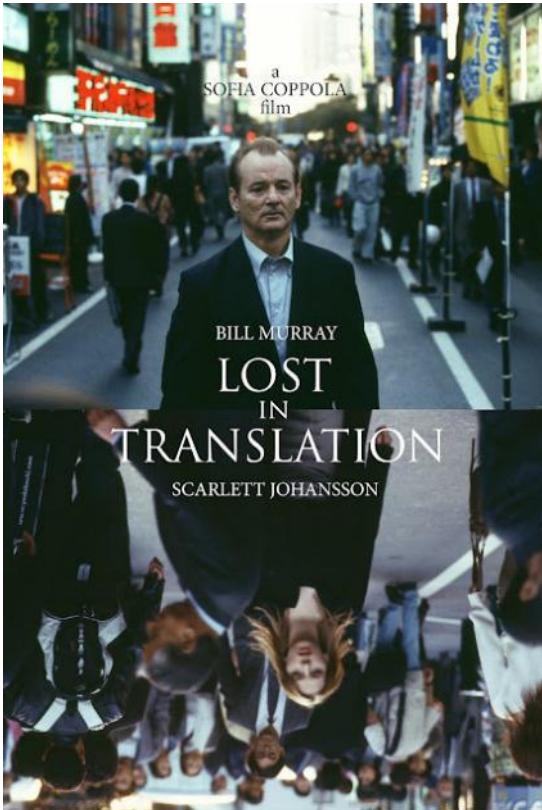


There is an ongoing translation of indications within surgical HCC

There is an ongoing translation to transplant from non surgical HCC



Systemic therapies are producing the most significant LT criteria expansion to date

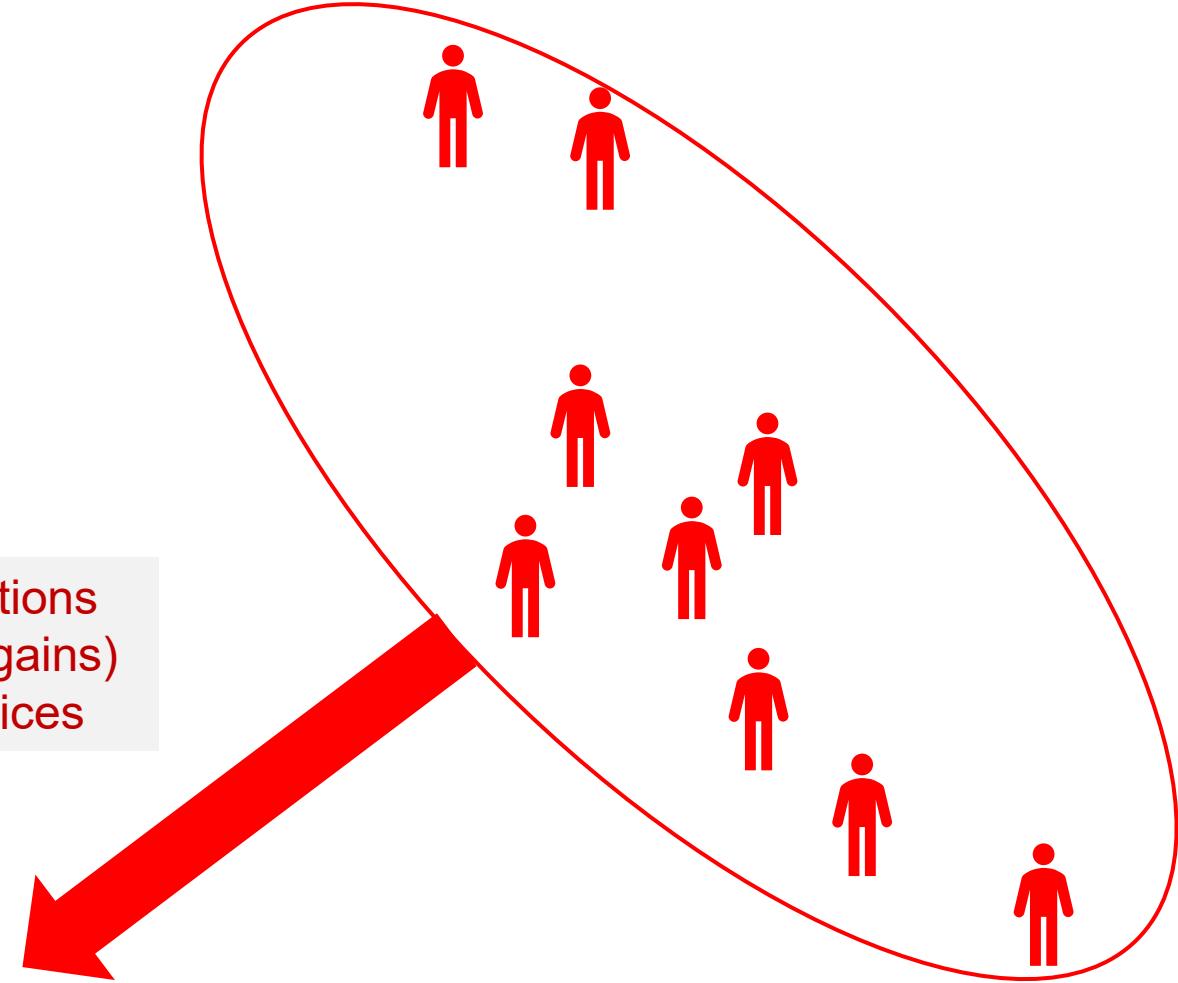


More than two decades later,
this is still one of the best film.
An exquisite dramedy that stays with you
long after the credits roll.

Urban Cinefile

Positive transformations
during translations (gains)
depend on our choices

**Thank you very much for
your attention**



vincenzo.mazzaferro@istitutotumori.mi.it
vincenzo.mazzaferro@unimi.it